

**POMALYST® (pomalidomide)**

**NDA # 204026**

Celgene Corporation

86 Morris Avenue

Summit, NJ 07901

Contact Information:

**1-908-673-9000**

**www.celgene.com**

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**1. GOALS**

The goals of the POMALYST risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to POMALYST.
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for POMALYST.

**2. REMS ELEMENTS**

**2.1. Elements to Assure Safe Use**

**2.1.1. Healthcare providers who prescribe POMALYST are specially certified.**

Celgene will ensure that healthcare providers who prescribe POMALYST are specially certified in the POMALYST REMS™ program. POMALYST® (pomalidomide) is available only through a restricted distribution program, POMALYST REMS™.

To become certified, each prescriber must complete the Prescriber Enrollment Form and agree to do the following:

- a. Provide patient counseling on the benefits and risks of POMALYST therapy, including risks described in the BOXED WARNINGS.
- b. Enroll each patient by completing and submitting to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customer care@celgene.com), fax (1-888-432-9325), or online (www.celgeneriskmanagement.com), a signed Patient-Physician Agreement Form (PPAF) identifying the patient's risk category (see PPAFs for all six risk categories) for each new patient. In signing the PPAF, each prescriber acknowledges that they understand that POMALYST is available only through the

- POMALYST REMS™ program, and that they must comply with program requirements.
- c. Provide contraception and emergency contraception counseling with each new prescription prior to and during POMALYST treatment.
  - d. Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions.
  - e. Report any pregnancies in female patients or female partners of male patients prescribed POMALYST immediately to Celgene Drug Safety (or Celgene Customer Care Center (1-888-423-5436)).
  - f. Complete a prescriber survey (phone or online) for every patient (new and follow-up), obtain a unique prescription authorization number for each prescription written, and include this authorization number on the prescription. The authorization number can be obtained by contacting the Celgene Customer Care Center, using the automated IVR system, or via the [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) website.
    - o For females of reproductive potential, authorization numbers are valid only for 7 days from date of last pregnancy test.
    - o Authorization numbers are valid for 30 days from the date it is issued for all other patients.
  - g. Facilitate compliance with the mandatory POMALYST REMS™ patient survey by instructing patients to complete the mandatory surveys (phone or online) at program specified frequencies.
  - h. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
  - i. Contact a pharmacy certified by the POMALYST REMS™ program to fill the POMALYST prescription.
  - j. Return all unused POMALYST brought in by patients to Celgene Customer Care.
  - k. Re-enroll patients in the POMALYST REMS™ program if POMALYST is required and previous therapy with POMALYST has been discontinued for 12 consecutive months.

Celgene will:

- 1. Ensure that the POMALYST REMS™ program materials including prescriber enrollment are available on the [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com) website or can be obtained by contacting Celgene Customer Care Center at 1-888-423-5436
- 2. Maintain a secure database of all POMALYST REMS™ certified prescribers.
- 3. Monitor to ensure that only POMALYST REMS™ certified prescribers are prescribing POMALYST.
- 4. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category when completing the PPAFs during the patient enrollment process:
  - a. **Adult female of reproductive potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
  - b. **Female child of reproductive potential:** all females under 18 years who are menstruating.

- c. **Adult female NOT of reproductive potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.
  - d. **Female child NOT of reproductive potential:** all females under 18 years who are not menstruating.
  - e. **Adult males 18 years or older**
  - f. **Male child under 18 years**
5. Monitor certified prescriber compliance with the POMALYST REMS™ program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with POMALYST.
  6. Institute corrective action and prevent the certified prescriber from prescribing POMALYST if the prescriber is found to be non-compliant with the POMALYST REMS™ program.
  7. Train POMALYST REMS™ program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to POMALYST if a pregnancy occurs.
  8. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax or online to confirm the patient's enrollment and signify that the prescriber and patient surveys can be taken to receive an authorization number for the POMALYST prescription (for all males, the PPAF is considered the initial survey). The authorization number is written on the POMALYST prescription.
  9. Ensure that, for subsequent prescriptions, the prescriber completes a telephone or online survey designed to look for signals of at-risk behavior (e.g., pending or outdated pregnancy test), report the patient's pregnancy test results, correct assignment of risk category, and confirm or re-enforce patient understanding of contraceptive requirements. The completion of the survey will allow the prescriber to obtain a new authorization number every time a prescription for POMALYST is written.

The following materials are part of the REMS, and are appended:

- [Prescriber Enrollment Form](#)
- [Patient Prescription Form](#)
- [Patient Prescription Form \(Veterans Administration\)](#)
- [Prescriber Guide to POMALYST REMS™ Program](#)
- [POMALYST REMS™ At-A-Glance](#)
- [Welcome Letter](#)
- [Celgene Risk Management.com website](#)

#### **2.1.2. POMALYST will only be dispensed by pharmacies that are specially certified.**

Celgene will ensure that POMALYST is only dispensed from POMALYST REMS™ program certified pharmacies. To become a certified pharmacy, the pharmacy must agree to do the following before filling a POMALYST prescription:

- a. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
- b. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional POMALYST.
- c. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing POMALYST prescription.
- d. Obtain a POMALYST REMS<sup>TM</sup> confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The POMALYST REMS<sup>TM</sup> confirmation number may be obtained using the following procedure:
  1. Enter the pharmacy identification number (NABP or DEA);
  2. Enter the prescription authorization number written on the prescription;
  3. Enter the number of capsules and milligram (mg) strength being dispensed;
  4. Dispense or ship the prescribed POMALYST within 24 hours of obtaining and recording the POMALYST REMS<sup>TM</sup> confirmation number and confirmation date.
- e. Dispense POMALYST only after a POMALYST REMS<sup>TM</sup> confirmation number is obtained. If no confirmation is obtained, then no POMALYST is dispensed. Contact the patient's physician and Celgene for further instruction.
- f. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
- g. For each patient receiving treatment, retain a record of each POMALYST prescription dispensed and the corresponding completed Education and Counseling Checklist.
- h. Complete the checklist that applies to the patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
- i. Provide counseling to patients and/or guardians of patients under 18 years of age receiving POMALYST treatment.
  - a. Counsel all patients and guardians of patients under 18 years of age on the following:
    1. The benefits and risks of POMALYST therapy.
    2. Not sharing POMALYST medication.
    3. Not donating blood while taking POMALYST, during dose interruptions, and for 4 weeks after stopping POMALYST.
    4. Not to break, chew, or open POMALYST capsules.
    5. Instructions on POMALYST dose and administration.
    6. To read the POMALYST REMS<sup>TM</sup> program education materials and encourage compliance with the requirements.
  - b. In addition to above, counsel **Females of Reproductive Potential** on the following:
    1. The potential for embryo-fetal toxicity with exposure to POMALYST.
    2. Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse.
    3. Continuing to use 2 forms of birth control if POMALYST therapy is interrupted and for at least 4 weeks after therapy is discontinued.
    4. Obtaining a pregnancy test weekly during the first 4 weeks of POMALYST use, then a repeat pregnancy test every 4 weeks in females with regular

menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.

5. The need to stop taking POMALYST and notify their POMALYST prescriber immediately if they become pregnant or suspect they may be pregnant.
- c. In addition to items listed for all patients above, counsel **Males** receiving POMALYST treatment about the potential for embryo-fetal toxicity with exposure to POMALYST and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving POMALYST has had a successful vasectomy.
  1. The need to not donate sperm while taking POMALYST, during dose interruptions, and for 4 weeks after stopping POMALYST.
- d. Counsel the **Parent or legal guardian of Female Child NOT of reproductive potential** who is receiving POMALYST treatment about the need to inform their POMALYST prescriber when the child begins menses.

Before a certified pharmacy dispenses POMALYST, Celgene will train the appropriate pharmacy staff:

1. About the POMALYST REMS<sup>TM</sup> program
2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to POMALYST if a pregnancy occurs.

The following materials are part of the REMS and are appended:

- [Pharmacy Guide to the POMALYST REMS<sup>TM</sup> Program](#)
- [Education and Counseling Checklist for Pharmacies](#)
- [Celgene REMS Programs Pharmacy Training: the POMALYST REMS<sup>TM</sup> Program](#)
- [Pharmacy Certification Quiz \(the POMALYST REMS<sup>TM</sup> Program\)](#)

**2.1.3. Celgene will ensure that POMALYST will only be dispensed to patients enrolled in the POMALYST REMS<sup>TM</sup> program with evidence or other documentation of safe-use conditions.**

Celgene will ensure that all patients treated with POMALYST are enrolled by a certified prescriber. The prescriber will enroll the patient by completing Patient-Physician Agreement Form and submitting the form via mail (86 Morris Avenue, Summit, NJ 07901), fax (1-888-432-9325), email (customer@celgene.com) or online (www.celgeneriskmanagement.com) for each patient who receives POMALYST. Each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- a. acknowledging that he or she understands that:
  - i. severe birth defects or death to an unborn baby may occur if a female becomes pregnant while she is receiving POMALYST;

- ii. POMALYST must not be shared with anyone, even someone with similar symptoms;
- iii. POMALYST must be kept out of the reach of children and should NEVER be shared with females who are able to have children;
- iv. they cannot donate blood while receiving POMALYST, including dose interruptions, and for 4 weeks after stopping POMALYST;
- v. they might be asked to participate in the POMALYST Pregnancy Exposure Registry; and
- vi. they may be contacted by Celgene about following the rules of the REMS.

In addition, each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- i. agreeing to return unused POMALYST to Celgene or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them;
- ii. agreeing to participate in a monthly (telephone or online) survey while on POMALYST (with the exception of Adult Females Not of Reproductive Potential who are required to take a survey once every six months); and
- iii. reviewing the POMALYST REMS™ program educational materials and asking their prescriber any questions that have not been answered.

In addition, **Females and guardians of female children** must attest to their understanding of their/their child's reproductive potential, as categorized by the prescribing physician.

**Females of Reproductive Potential and guardians of Female Children of Reproductive Potential** will attest that they/their child:

- a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving POMALYST therapy and for at least 4 weeks after completely stopping POMALYST therapy;
- b. must not take POMALYST if pregnant, breastfeeding a baby, or not using birth control as defined in the REMS;
- c. will, unless abstinent, use contraception as defined within the REMS: for at least 4 weeks before starting POMALYST, while receiving POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST;
- d. will have pregnancy testing done as ordered by the certified prescriber within 10 to 14 days and 24 hours prior to starting POMALYST, every week for at least the first 4 weeks of POMALYST therapy, and then every 4 weeks if the Female of Reproductive Potential has regular menstrual cycles, or every 2 weeks if the Female of Reproductive Potential has irregular menstrual cycles, while receiving POMALYST;
- e. will immediately stop taking POMALYST and inform the certified prescriber if the patient becomes pregnant, misses a menstrual period, experiences unusual menstrual bleeding, stops using contraception, or thinks for any reason that she might be pregnant; if the prescriber is not available, the Female of Reproductive Potential or guardian of a Female Child of Reproductive Potential can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception.

**Males or guardians of Males** will attest that they/their child will:

- a. never have unprotected sexual contact with a female who can become pregnant;
- b. wear a latex or synthetic condom every time the male patient has sexual contact with a female who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving POMALYST treatment, during dose interruptions, and for 4 weeks after the male patient stops taking POMALYST, even if the patient has had a successful vasectomy; and
- c. inform their certified prescriber if the male patient has unprotected sexual contact with a female who can become pregnant, or if they think for any reason that the male patient's sexual partner might be pregnant; the male patient or guardian of an underage male patient can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception;
- d. not donate sperm while taking (including dose interruptions) and for 4 weeks after stopping POMALYST.

The following appended materials are part of the REMS:

- [Patient-Physician Agreement Form for Adult Males](#)
- [Patient-Physician Agreement Form for Male Child](#)
- [Patient-Physician Agreement Form for Adult Female Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant](#)
- [Patient-Physician Agreement Form for a Female Child Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form for a Female Child Who Can Get Pregnant](#)
- [Patient Guide to POMALYST REMS™ Program](#)
- [Patient Survey Reminder Card](#)
- [POMALYST Risk Evaluation and Mitigation Strategy \(REMS\)™ program education and prescribing safety kit](#)
- [POMALYST REMS™ Patient Resource Pack Envelope](#)

**2.1.4. Female patients or female partners of male patients receiving POMALYST who report a pregnancy that occurred during POMALYST therapy will be enrolled in the POMALYST Pregnancy Exposure Registry.**

Upon receiving a report of pregnancy from the POMALYST REMS™ program, Celgene Pregnancy Prevention Plan programs in the rest of the world, clinical trials, or directly from a prescriber, a pharmacy, or a patient, Celgene will enroll the female patient or female partner of the male patient taking POMALYST into the POMALYST Pregnancy Exposure Registry. The objectives of the registry are to monitor pregnancy outcomes in female patients of reproductive potential and male patients' female partners who are exposed to POMALYST and to understand why the POMALYST REMS™ program was unsuccessful.

## **2.2. Implementation System**

The implementation system will include the following:

- 1) Celgene will maintain a secure database of all certified entities, including enrolled patients and certified prescribers and pharmacies to monitor and evaluate implementation of the elements provided for in Sections 2.1.1, 2.1.2, and 2.1.3.
- 2) Celgene will monitor pharmacy certification compliance and address deviations by monitoring real time dispensing activity and conducting pharmacy audits.
  - a. The Celgene Customer Care Center will monitor the certified pharmacies in the manner described in the REMS supporting document to ensure only enrolled and authorized patients are receiving POMALYST. If a certified pharmacy is found to be non-compliant with the POMALYST REMS<sup>TM</sup> program, Celgene will institute corrective action and may de-activate pharmacies for which re-training has proven ineffective, removing them from the POMALYST REMS<sup>TM</sup> program.
  - b. Celgene will perform regular audits of contract pharmacies participating in the POMALYST REMS<sup>TM</sup> program. For pharmacies that have been in the program for more than two years, Celgene will perform a risk-based assessment to select which pharmacies will be audited. The POMALYST REMS<sup>TM</sup> program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene.
- 3) Celgene will monitor and ensure that the prescriptions are filled within the allowed timeframes.
- 4) Celgene Customer Care Center will address customer complaints received that are related to the POMALYST REMS<sup>TM</sup> program and distribution and dispensing of POMALYST.
- 5) Celgene will maintain a reporting and collection system for safety information that includes a process to monitor pregnancy testing results and pregnancy outcomes (should one occur) through the POMALYST Pregnancy Exposure Registry and to understand why the POMALYST REMS<sup>TM</sup> program was unsuccessful for the pregnancy case in question.
- 6) Based on monitoring and evaluation of these elements to assure safe use, Celgene will take reasonable steps to work to improve implementation of these elements as applicable.
- 7) Celgene will develop and follow written procedures related to the implementation of the REMS.

## **2.3. Timetable for Submission of Assessment Reports**

Assessment Reports will be submitted annually from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment. Celgene will submit each assessment so it will be received by the FDA on or before the due date.



# POMALYST® (pomalidomide) Patient Prescription Form

Today's Date _____ Date Rx Needed _____	Prescriber Name _____
Patient Last Name _____ Patient First Name _____	State License Number _____
Phone Number (____) _____	Prescriber Phone Number (____) _____ Ext. ____
Shipping Address _____	Fax Number (____) _____
City _____ State _____ Zip _____	Prescriber Address _____
Date of Birth _____ Patient ID# _____	_____
Language Preference: <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Other _____	City _____ State _____ Zip _____
Best Time to Call Patient: <input type="checkbox"/> AM _____ <input type="checkbox"/> PM _____	<b>Patient Type From PPAF (Check one)</b>
Patient Diagnosis (ICD-10 Code) _____	<input type="checkbox"/> Adult Female – NOT of Reproductive Potential
Patient Allergies _____	<input type="checkbox"/> Adult Female – Reproductive Potential
_____	<input type="checkbox"/> Adult Male
Other Current Medications _____	<input type="checkbox"/> Female Child – Not of Reproductive Potential
	<input type="checkbox"/> Female Child – Reproductive Potential
	<input type="checkbox"/> Male Child

## PRESCRIPTION INSURANCE INFORMATION

(Fill out entirely and fax a copy of patient's insurance card, both sides)

Primary Insurance \_\_\_\_\_

Insured \_\_\_\_\_

Policy # \_\_\_\_\_

Group # \_\_\_\_\_

Phone # \_\_\_\_\_

Rx Drug Card # \_\_\_\_\_

Secondary Insurance \_\_\_\_\_

Insured \_\_\_\_\_

Policy # \_\_\_\_\_

Group # \_\_\_\_\_

Phone # \_\_\_\_\_

Rx Drug Card # \_\_\_\_\_

**TAPE PRESCRIPTION HERE PRIOR TO FAXING**

**REFERRAL, OR COMPLETE THE FOLLOWING:**

**Recommended Starting Dose:** See below for dosage

**Multiple Myeloma:** The recommended starting dose of POMALYST is 4 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings

### POMALYST

Dose	Quantity	Directions
<input type="checkbox"/> 1 mg _____	_____	
<input type="checkbox"/> 2 mg _____	_____	
<input type="checkbox"/> 3 mg _____	_____	
<input type="checkbox"/> 4 mg _____	_____	
<input type="checkbox"/> Dispense as Written		<input type="checkbox"/> Substitution Permitted

**NO REFILLS ALLOWED (Maximum Quantity = 28 days)**

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For further information on POMALYST, please refer to the full  
Prescribing Information

## **How to Fill a POMALYST® (pomalidomide) Prescription**

1. Healthcare provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form
4. HCP obtains POMALYST REMS™ authorization number
5. HCP provides authorization number on patient prescription form
6. HCP faxes form, including prescription, to one of the Celgene Certified Pharmacy Network participants (see below)
7. HCP advises patient that a representative from the certified pharmacy will contact them
8. Certified pharmacy conducts patient education
9. Certified pharmacy obtains confirmation number
10. Certified pharmacy ships POMALYST to patient with MEDICATION GUIDE

**Please see [www.Celgene.com/PharmacyNetwork](http://www.Celgene.com/PharmacyNetwork) for the list of pharmacy participants**

Information about POMALYST and the POMALYST REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

# POMALYST® (pomalidomide)

## Patient Prescription Form – Veterans Administration (VA) ONLY

Today's Date _____ Date Rx Needed _____	Prescriber Name _____
Patient Last Name _____ Patient First Name _____	State License Number _____
Phone Number (____) _____	Prescriber Phone Number (____) _____ Ext. ____
Shipping Address _____	Fax Number (____) _____
City _____ State _____ Zip _____	Prescriber Address _____
Date of Birth _____ Patient ID# _____	_____
Language Preference: <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Other _____	City _____ State _____ Zip _____
Best Time to Call Patient: <input type="checkbox"/> AM _____ <input type="checkbox"/> PM _____	
Patient Diagnosis (ICD-10 Code) _____	<b>Patient Type From PPAF (Check one)</b>
Patient Allergies _____	<input type="checkbox"/> Adult Female – NOT of Reproductive Potential
_____	<input type="checkbox"/> Adult Female – Reproductive Potential
Other Current Medications _____	<input type="checkbox"/> Adult Male
_____	<input type="checkbox"/> Female Child – Not of Reproductive Potential
	<input type="checkbox"/> Female Child – Reproductive Potential
	<input type="checkbox"/> Male Child

**VA Pharmacy Information (Fill out entirely)**

VA Name \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

VA Pharmacist Name \_\_\_\_\_

Phone # \_\_\_\_\_

Fax # \_\_\_\_\_

McKesson Specialty Distribution Account #

\_\_\_\_\_

**Shipping Information**

Check below for direct delivery to patient. If any information is omitted, product will be shipped to the VA Pharmacy.

☐ Patient

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_

For further information on POMALYST, please refer to the full Prescribing Information

***TAPE PRESCRIPTION HERE PRIOR TO FAXING***

***REFERRAL, OR COMPLETE THE FOLLOWING:***

**Recommended Starting Dose:** See below for dosage

**Multiple Myeloma:** The recommended starting dose of POMALYST is 4 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings

**POMALYST**

Dose	Quantity	Directions
<input type="checkbox"/> 1 mg	_____	_____
<input type="checkbox"/> 2 mg	_____	_____
<input type="checkbox"/> 3 mg	_____	_____
<input type="checkbox"/> 4 mg	_____	_____

## *How to Fill POMALYST® (pomalidomide)*

### *Prescription in the Veterans Administration (VA)*

1. Healthcare Provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form (include cell number for patient if possible)
4. HCP obtains POMALYST REMS™ authorization number
5. HCP provides authorization number on patient prescription form
6. HCP sends prescription to the VA Pharmacy

The following information must be filled in:

- **Rx must include McKesson Specialty Distribution account number**
- **Rx must include VA address** (Name, Street, City, State, ZIP)
- **Rx must include VA Pharmacist contact information** (Name, Phone and Fax #)

7. VA Pharmacist faxes the form, including prescription, to:

**The POMALYST REMS™ certified OncologyRx Care Advantage Specialty at 1-855-637-9446**

8. HCP advises patient that a representative from POMALYST REMS™ certified pharmacy will be in contact
9. The POMALYST REMS™ certified OncologyRx Care Advantage Pharmacist conducts patient education
10. The POMALYST REMS™ certified OncologyRx Care Advantage Pharmacist obtains confirmation number
11. The POMALYST REMS™ certified OncologyRx Care Advantage Pharmacist ships POMALYST to the VA Pharmacy or directly to the patient with MEDICATION GUIDE
12. VA Pharmacist gives POMALYST to VA patient with MEDICATION GUIDE

# *POMALYST REMS™ Veterans Administration (VA) Pharmacy*

**OncologyRx Care Advantage** Phone: 1-855-637-9433

Fax: 1-855-637-9446

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Information about POMALYST and the POMALYST REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com).



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REMS-POM14362

## **Prescriber Guide to**

## **((POMALYST REMS™ logo))**

### **Risk Evaluation and Mitigation Strategy (REMS)™ Program**

Due to its structural similarity to thalidomide, a known teratogen, POMALYST® (pomalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program.

This guide contains important information for prescribers about:

- The risks of POMALYST, including a boxed warning for
  - Embryo-fetal toxicity
  - Venous thromboembolism
- The POMALYST REMS™ program
  - Prescriber Certification
  - Patient Enrollment
  - Contraceptive Requirements and Counseling for Patients
  - Initial and Subsequent Prescription Requirements

#### **POMALYST REMS™ Resources for Prescribers Include:**

- Prescriber Guide to POMALYST REMS™ Program



- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for POMALYST

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## About POMALYST® (pomalidomide)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

### Risks of POMALYST

**POMALYST has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism.**

**Due to the fact that it is an analogue of thalidomide, a known teratogen,** POMALYST is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE) occurred in patients with multiple myeloma treated with pomalidomide. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient's underlying risk factors.

## **The POMALYST REMS™ program**

To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a restricted distribution program called “POMALYST Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST in the POMALYST REMS™ program.

In order to receive POMALYST, all patients must be enrolled in POMALYST REMS™ and agree to comply with the requirements of the POMALYST REMS™ program. Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

### **Key points of the POMALYST REMS™ program**

#### **Prescriber**

- The prescriber enrolls and becomes certified with Celgene for the POMALYST REMS™ program
- The prescriber counsels patient on benefits and risks of POMALYST
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends POMALYST prescription to a certified pharmacy

#### **Pharmacy**

- The pharmacy certifies with Celgene for POMALYST REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

## **POMALYST REMS™ patient enrollment**

- Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with POMALYST REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the POMALYST® (pomalidomide) Patient-Physician Agreement Form in the language of their choice

### **Help Ensure Timely Processing of Each Prescription**

#### **Fill Out Form as Directed**

- Write only in the designated areas on the POMALYST® (pomalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

#### **Instructions for Female Patients**

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

#### **Instructions for Minors**

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

#### **Instructions for Incompetent Adult Patients**

- For an incompetent adult patient, an authorized representative must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form

## POMALYST REMS™ patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient

### Send in Completed Forms

- Send the completed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the POMALYST® (pomalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

**Note:** If therapy with POMALYST is discontinued for 12 consecutive months, the patient must enroll again in the POMALYST REMS™ program. Follow the above procedures to re-enroll the patient.

## Initial prescription requirements

### ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with POMALYST® (pomalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with POMALYST
- Provide counseling not to share POMALYST capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of POMALYST, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the POMALYST REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open POMALYST capsules
- Instruct patients to return unused POMALYST capsules for disposal to Celgene or to their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them

### FEMALE PATIENTS

Determine if female patient is of reproductive potential

<b>Two categories:</b>
<b>1. Females of Reproductive Potential</b> <ul style="list-style-type: none"><li>• All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category</li></ul>
<b>2. Females Not of Reproductive Potential</b> <ul style="list-style-type: none"><li>• Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating</li></ul>

## 1. Females of Reproductive Potential

### Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for POMALYST® (pomalidomide) and again within 24 hours prior to writing an initial prescription for POMALYST even if continuous abstinence is the chosen method of birth control
  - The pregnancy test must be sensitive to at least 50 mIU/mL
  - Pregnancy testing should occur weekly during the first 4 weeks of use
  - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
  - If a patient misses her period or if there is any abnormality in menstrual bleeding, POMALYST should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, POMALYST must be immediately discontinued.** Any suspected embryo-fetal exposure to POMALYST must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with POMALYST

### Patient Counseling on Contraception Requirements

#### Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

### Effective Methods of Birth Control to Use Together



Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom + Diaphragm
Tubal ligation (having your tubes tied)	Cervical cap
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

**Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.**

- **Unacceptable forms of contraception:**
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield\*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

\*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

## 2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy

- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

## **MALE PATIENTS**

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking POMALYST therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of POMALYST

## Initial mandatory confidential survey

### Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

### Males

- Males do not need to take the initial survey

### Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
  - Prescriber's identification number
  - Patient's identification number
  - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
  - Average daily dose
  - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

### **Additional Information for the Prescriber**

- Healthcare provider must send the prescription to a POMALYST REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

## Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for POMALYST® (pomalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

### FEMALE PATIENTS

- Provide counseling as outlined in the “FEMALE PATIENTS” section on pages 7-10
- Follow pregnancy test requirements as outlined in the “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
  - Before prescription is obtained
  - Monthly
    - Adult females of reproductive potential
    - All female children
  - Every 6 months
    - Adult females not of reproductive potential

### MALE PATIENTS

- Provide patient counseling as outlined in the “MALE PATIENTS” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
  - Males do not complete an initial survey

## **After the last dose of POMALYST® (pomalidomide)**

After patients have stopped taking POMALYST, they must do the following:

### **ALL PATIENTS**

- Must not share POMALYST capsules—especially with females of reproductive potential
- Must return any unused POMALYST capsules for disposal to Celgene or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Must not donate blood for 4 weeks after stopping POMALYST

### **FEMALE PATIENTS**

- Must not get pregnant for at least 4 weeks after stopping POMALYST by using the appropriate contraceptives each time engaging in sexual activity with a male

### **MALE PATIENTS**

- Must use a latex or synthetic condom for 4 weeks after stopping POMALYST
- Must not donate sperm for 4 weeks after stopping POMALYST

## Ordering English and non-English materials

**CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436**

- Materials are available in 16 languages and include:
  - POMALYST® (pomalidomide) Patient-Physician Agreement Forms
  - Patient Guide to POMALYST REMS™ Program
  - Mandatory confidential survey forms

### **Available languages:**

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- POMALYST® (pomalidomide) Patient-Physician Agreement Forms, Patient Guide to POMALYST REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

#### **Prescriber's:**

Name

Identification Number

Full Address

Fax Number

#### **Patient's:**

Name

Full Address

Phone Number

Date of Birth

Identification Number

Diagnosis (most recent version of ICD code)

## **Adverse drug experience reporting procedure for healthcare professionals**

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST® (pomalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods.

### **REPORTING TO CELGENE**

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

### **REPORTING TO THE FDA**

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about POMALYST<sup>®</sup> (pomalidomide) and the POMALYST REMS<sup>™</sup> program, please visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

**POMALYST is only available under a restricted distribution program, POMALYST REMS<sup>™</sup>.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

((Celgene logo)) ((POMALYST REMS logo)) ((POMALYST logo))

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((POMALYST REMS™ logo))

## ***At-A-Glance***

### **Important information about POMALYST® (pomalidomide) and the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program**

- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called “POMALYST REMS™”
- Only prescribers and pharmacies certified by the POMALYST REMS™ program can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

For more information about POMALYST and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

((Celgene logo))      ((POMALYST REMS logo))      ((POMALYST logo))

### Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for POMALYST® (pomalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
  - **Males (adults and children)**
  - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
  - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
  - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
  - You will need to enter the following information:
    - Prescriber's identification number
    - Patient's identification number
    - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
    - Average daily dose
    - Total number of days supplied (cannot exceed 28 days)
7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7

days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.

8. Send the prescription to a certified pharmacy.

### Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
  - Monthly:
    - **Males (adults and children)**
    - **Females of reproductive potential (adults and children)**
    - **Female children not of reproductive potential**
  - Every 6 months:
    - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
  - You will need to enter the following information:
    - Prescriber's identification number
    - Patient's identification number
    - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
    - Average daily dose
    - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.

POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

[Front]

## **((POMALYST REMS™ logo)) Prescriber Enrollment Form**

All prescribers **must** be certified to prescribe POMALYST® (pomalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for POMALYST REMS™ certification.
2. Agree to steps on the following page that **must** be followed with every patient.

To submit this form electronically, please go to [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com).

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that **must** be followed with every patient.

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

((POMALYST logo))

[Back]

## POMALYST REMS™ Prescriber Enrollment Form

**When prescribing POMALYST® (pomalidomide), I agree to:**

- Provide patient counseling on the benefits and risks of POMALYST therapy, including Boxed Warnings
- Submit a completed POMALYST® (pomalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during POMALYST treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed POMALYST immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a POMALYST REMS™ certified pharmacy to fill the prescription
- Return to Celgene all POMALYST capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all POMALYST capsules to Celgene Corporation or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Re-enroll patients in the POMALYST REMS™ program if POMALYST is required and previous therapy with POMALYST has been discontinued for 12 consecutive months



**Please fill out the spaces below completely.**

Prescriber Name \_\_\_\_\_

Degree: MD/DO/PA/NP/Fellow/Medical Resident Specialty \_\_\_\_\_

Prescriber Identification Number (eg, DEA Number, Social Security Number, NPI Number, etc.)  
\_\_\_\_\_

**Please indicate which office(s) will receive POMALYST REMS™ materials and updates:**

• Primary Office Name \_\_\_\_\_

Attention \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_

Phone \_\_\_\_\_ Ext. \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

• Secondary Office Name \_\_\_\_\_

Attention \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_

Phone \_\_\_\_\_ Ext. \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

**I understand that if I fail to comply with all requirements of the POMALYST REMS™ program, my prescriptions for POMALYST® (pomalidomide) will not be honored at certified pharmacies.**

Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_

**Return this form to the Celgene Customer Care Center via fax or mail.**

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436**

Fax: **1-888-432-9325**

**[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**

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REMS-POM13279

## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Female Who Can Get Pregnant

Please read the following statements carefully.

**Your doctor has prescribed POMALYST for you. POMALYST is available only through a restricted distribution program called POMALYST Risk Evaluation and Mitigation Strategy(REMS)™. Before taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS™ program.**

**If you are pregnant or become pregnant while taking POMALYST, it is important for you to know that your unborn baby can have severe birth defects or even die.**

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

### INSTRUCTIONS

***Before starting your treatment with POMALYST, you will need to:***

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.

3. Keep a copy of this form for your records.

**Authorized Representatives:**

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient.

For more information, visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

**BAR CODE HERE**

# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- ☐ POMALYST can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
- ☐ I am not pregnant now and will not get pregnant while being treated with POMALYST
- ☐ It is possible for me to get pregnant if:
  - I am having my period (am menstruating), or
  - My period has stopped because of my treatment
  - And I have sex with a male
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ I am not breastfeeding now and will not breastfeed while being treated with POMALYST
- ☐ My POMALYST prescription is **only** for me and is not to be shared with others
- ☐ I have read and understood the POMALYST Patient Guide to POMALYST REMS™ program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- ☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ☐ I may be contacted by Celgene to assist with the POMALYST REMS™ program
- ☐ I will NOT donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Female Who Can Get Pregnant

- ☐ I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my doctor. My doctor may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	+
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Diaphragm
	Cervical cap

- ☐ I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male:
- Starting at least 4 weeks before taking POMALYST
  - While taking POMALYST
  - During breaks (dose interruptions)
  - For at least 4 weeks after stopping POMALYST

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Female Who Can Get Pregnant

- ☐ I will have pregnancy tests—performed by my healthcare provider—according to the schedule listed below:
  - 10 to 14 days before receiving my first prescription for POMALYST, and again 24 hours before receiving my first prescription for POMALYST
  - Every week during the first 4 weeks of my treatment with POMALYST
  - Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if I have an irregular menstrual cycle
- ☐ I will have these pregnancy tests even if I do not get my period because of my treatment
- ☐ I will need to take another pregnancy test performed by my healthcare provider if my medication is not dispensed within 7 days of taking my pregnancy test
- ☐ I will stop taking POMALYST and call my doctor right away if I:
  - Become pregnant while taking POMALYST, or
  - Miss my period or have unusual menstrual bleeding, or
  - Stop using birth control, or
  - Think—**for any reason**—that I am pregnant or may be pregnant
- ☐ If I become pregnant or think I may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- ☐ I will complete the mandatory confidential monthly survey while taking POMALYST
- ☐ I will keep my POMALYST prescription out of the reach of children
- ☐ I will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused POMALYST capsules can also be returned to my POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to me

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Get Pregnant

### Section 2. Authorization

#### I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me with information about POMALYST or my condition
- ☐ This authorization will remain in effect for 12 months after I stop POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the POMALYST REMS™ program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in POMALYST REMS™ program. I understand that by refusing to participate in POMALYST REMS™ program, I will not be able to receive POMALYST. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, **I authorize my healthcare provider to begin my treatment with POMALYST**



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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Female Who Can Get Pregnant

#### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the POMALYST REMS™ program, I will not be able to receive POMALYST. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.**

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category  Menstruating:  Surgical Menopause:  Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:  Signature Date:		Prescriber's Signature:  Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Female Who Can Not Get Pregnant

Please read the following statements carefully.

**Your doctor has prescribed POMALYST for you. POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS™ program.**

**Any unborn baby of a female taking POMALYST can have severe birth defects or even die.**

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

#### INSTRUCTIONS

***Before starting your treatment with POMALYST, you will need to:***

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

#### **Authorized Representatives:**

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene**

**Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- ☐ POMALYST can cause severe birth defects or death to unborn babies of females taking POMALYST
- ☐ I am not pregnant
- ☐ I am not able to get pregnant because:
  - I have had both of my ovaries and/or my uterus removed, or
  - I have been in natural menopause for at least 2 years
- ☐ My POMALYST prescription is **only** for me and is not to be shared with others
- ☐ I have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- ☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ☐ I may be contacted by Celgene to assist with the POMALYST REMS™ program

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

### I will:

- ☐ I will complete the mandatory confidential survey every 6 months while taking POMALYST
- ☐ I will keep my POMALYST prescription out of the reach of children
- ☐ I will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused POMALYST capsules can also be returned to my POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to me

### I will not:

- ☐ I will **not** share my POMALYST capsules with anyone even if they have symptoms like mine
- ☐ I will **not** donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

### Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me with information about POMALYST or my condition
- ☐ This authorization will remain in effect for 12 months after I stop POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the POMALYST REMS™ program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the POMALYST REMS™ program. I understand that by refusing to participate in POMALYST REMS™ program, I will not be able to receive POMALYST. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I **authorize my healthcare provider to begin my treatment with POMALYST**



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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Female Who Can Not Get Pregnant

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the POMALYST REMS™ program, I will not be able to receive POMALYST. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with POMALYST and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.**

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category  Menstruating:  Surgical Menopause:  Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Female Child Who Can Get Pregnant

Please read the following statements carefully.

**Your doctor has prescribed POMALYST for your child.\* POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, patients must read and agree to all of the instructions in the POMALYST REMS™ program.**

**If your child is pregnant or becomes pregnant while taking POMALYST, it is important to know that the unborn baby can have severe birth defects or even die.**

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

### INSTRUCTIONS

***Before** your child starts treatment with POMALYST, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- ☐ POMALYST can cause severe birth defects or death to the unborn baby if my child is pregnant or becomes pregnant during treatment
- ☐ My child is not pregnant and will not get pregnant while being treated with POMALYST
- ☐ It is possible for my child to get pregnant if:
  - She has her period (is menstruating) or has shown any sign of puberty, or
  - Her period has stopped because of treatment
  - And she has sex with a male
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ My child is not breastfeeding and will not breastfeed while being treated with POMALYST
- ☐ My child's POMALYST prescription is **only** for her and is not to be shared with others
- ☐ We have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- ☐ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ☐ We may be contacted by Celgene to assist with the POMALYST REMS™ program
- ☐ My child will NOT donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### I will tell my child that:

- ☐ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her doctor. Her doctor may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	Diaphragm
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

- ☐ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:
- Starting at least 4 weeks before taking POMALYST
  - While taking POMALYST
  - During breaks (dose interruptions)
  - For at least 4 weeks after stopping POMALYST

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Female Child Who Can Get Pregnant

- ☐ She must have pregnancy tests—performed by her healthcare provider—according to the schedule listed below:
- 10 to 14 days before receiving her first prescription for POMALYST, and again 24 hours before receiving her first prescription for POMALYST
  - Every week during the first 4 weeks of her treatment with POMALYST
  - Every 4 weeks during the rest of her treatment if she has a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if she has an irregular menstrual cycle
- ☐ She must have these pregnancy tests even if she does not get her period because of her treatment
- ☐ She must take another pregnancy test performed by her healthcare provider if her medication is not dispensed within 7 days of taking her pregnancy test
- ☐ She must stop taking POMALYST and I will call her doctor right away if she:
- Becomes pregnant while taking POMALYST, or
  - Misses her period or has unusual menstrual bleeding, or
  - Stops using birth control, or
  - Thinks—**for any reason**—that she is pregnant or may be pregnant
- ☐ If she becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- ☐ We will complete the mandatory confidential monthly survey while she is taking POMALYST
- ☐ We will keep her POMALYST prescription out of the reach of other children
- ☐ We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### Section 2. Authorization

#### I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about POMALYST or my child's condition
- ☐ This authorization will remain in effect for 12 months after my child stops POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the POMALYST REMS™ program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the POMALYST REMS™ program. I understand that by refusing to have my child participate in the POMALYST REMS™ program, she will not be able to receive POMALYST. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with POMALYST**



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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Get Pregnant

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the POMALYST REMS™ program, she will not be able to receive POMALYST. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.**

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category  Menstruating:  Surgical Menopause:  Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Female Child Who Can Not Get Pregnant

Please read the following statements carefully.

**Your doctor has prescribed POMALYST for your child.\* POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, patients must read and agree to all of the instructions in the POMALYST REMS™ program.**

**Any unborn baby of a girl taking POMALYST can have severe birth defects or even die.**

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

### INSTRUCTIONS

***Before your child starts treatment with POMALYST, you will need to:***

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

#### I understand and confirm that:

- ☐ POMALYST can cause severe birth defects or death to unborn babies of females taking POMALYST
- ☐ My child is not pregnant
- ☐ My child is not able to get pregnant because she has not yet started her period (is not menstruating)
- ☐ My child's POMALYST prescription is **only** for her and is not to be shared with others
- ☐ We have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- ☐ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ☐ We may be contacted by Celgene to assist with the POMALYST REMS™ program

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Female Child Who Can Not Get Pregnant

### I will tell my child that:

- ☐ We will complete the mandatory confidential monthly survey while my child is taking POMALYST
- ☐ We will keep my child's POMALYST prescription out of the reach of other children
- ☐ We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child
- ☐ She must **not** share her POMALYST capsules with anyone even if they have symptoms like hers
- ☐ She must **not** donate blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

**BAR CODE HERE**

# POMALYST® (pomalidomide) Patient-Physician Agreement

## Female Child Who Can Not Get Pregnant

### Section 2. Authorization

#### I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about POMALYST or my child's condition
- ☐ This authorization will remain in effect for 12 months after my child stops POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the POMALYST REMS™ program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the POMALYST REMS™ program. I understand that by refusing to have my child participate in the POMALYST REMS™ program, she will not be able to receive POMALYST. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with POMALYST**



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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Female Child Who Can Not Get Pregnant

#### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the POMALYST REMS™ program, she will not be able to receive POMALYST. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with POMALYST and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.**

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category  Menstruating:  Surgical Menopause:  Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

**BAR CODE HERE**

## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Male

Please read the following statements carefully.

**Your doctor has prescribed POMALYST for you. POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS™ program.**

**If a female you have sex with is pregnant or becomes pregnant by you while you are taking POMALYST, it is important for you to know that your unborn baby can have severe birth defects or even die.**

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

### INSTRUCTIONS

*Before starting your treatment with POMALYST, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

### Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient.

For more information, visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

BAR CODE HERE



# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Male

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

### Section 1. Patient Agreement

**I understand and confirm that:**

- ☐ POMALYST can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- ☐ My semen may contain POMALYST even after I stop treatment. I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ My POMALYST prescription is **only** for me and is not to be shared with others
- ☐ I have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- ☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ☐ I may be contacted by Celgene to assist with the POMALYST REMS™ program

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Adult Male

- ☐ I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- ☐ I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
  - While taking POMALYST
  - During breaks (dose interruptions)
  - For 4 weeks after stopping POMALYST
- ☐ I will call my doctor right away if I:
  - Have unprotected sex with a female who is pregnant or who is able to get pregnant
  - Think—**for any reason**—that my sexual partner is pregnant or may be pregnant
- ☐ If my partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- ☐ I will complete the mandatory confidential monthly survey while taking POMALYST
- ☐ I will keep my POMALYST prescription out of the reach of children
- ☐ I will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused POMALYST capsules can also be returned to my POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to me

**BAR CODE HERE**

# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Male

- ☐ I will **not** share my POMALYST capsules with anyone even if they have symptoms like mine
- ☐ I will **not** donate blood or sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST

### Section 2. Authorization

#### I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me with information about POMALYST or my condition

**BAR CODE HERE**

# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Male

- ☐ This authorization will remain in effect for 12 months after I stop POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the POMALYST REMS™ program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the POMALYST REMS™ program. I understand that by refusing to participate in the POMALYST REMS™ program, I will not be able to receive POMALYST. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, **I authorize my healthcare provider to begin my treatment with POMALYST**



Pomalyst REMS™



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Adult Male

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the POMALYST REMS™ program, I will not be able to receive POMALYST. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.**

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature:
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Male Child

Please read the following statements carefully.

**Your doctor has prescribed POMALYST for your child.\* POMALYST is available only through a restricted distribution program called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™. Before taking POMALYST, patients must read and agree to all of the instructions in the POMALYST REMS™ program.**

**If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking POMALYST, it is important to know that the unborn baby can have severe birth defects or even die.**

POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the POMALYST Medication Guide.

### INSTRUCTIONS

***Before** your child starts treatment with POMALYST, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the POMALYST REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

\*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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## POMALYST® (pomalidomide) Patient-Physician Agreement

### Male Child

Please read the following statements carefully. Mark the box (with an “X”) if you agree with the statement. Please do not mark or write outside of designated areas.

#### Section 1. Patient Agreement

**I understand and confirm that:**

- ☐ POMALYST can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
- ☐ My child’s semen may contain POMALYST even after he stops treatment. He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ My child’s POMALYST prescription is **only** for him and is not to be shared with others
- ☐ We have read and understood the POMALYST Patient Guide to the POMALYST REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that POMALYST may cause
- ☐ My child’s healthcare provider has reviewed this information with us and answered any questions we have asked
- ☐ We may be contacted by Celgene to assist with the POMALYST REMS™ program

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Male Child

#### I will tell my child that:

- ☐ He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent passing of sperm)
- ☐ He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant:
  - While taking POMALYST
  - During breaks (dose interruptions)
  - For 4 weeks after stopping POMALYST
- ☐ I will call his doctor right away if he:
  - Has unprotected sex with a female who is pregnant or who is able to get pregnant
  - Thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
- ☐ If my child's partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- ☐ We will complete the mandatory confidential monthly survey while my child is taking POMALYST
- ☐ We will keep his POMALYST prescription out of the reach of other children
- ☐ We will return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give us a refund for the capsules my child did not take. Unused POMALYST capsules can also be returned to my child's POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to my child

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## POMALYST® (pomalidomide) Patient-Physician Agreement Form

### Male Child

- ☐ He must **not** share his POMALYST capsules with anyone even if they have symptoms like his
- ☐ He must **not** donate blood or sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST

#### Section 2. Authorization

**I understand and confirm that:**

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of POMALYST
  - Evaluate the effectiveness of the POMALYST REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me and my child with information about POMALYST or my child's condition

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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Male Child

- ☐ This authorization will remain in effect for 12 months after my child stops POMALYST. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the POMALYST REMS™ program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the POMALYST REMS™ program. I understand that by refusing to have my child participate in the POMALYST REMS™ program, he will not be able to receive POMALYST. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with POMALYST**



Pomalyst REMS™



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# POMALYST® (pomalidomide) Patient-Physician Agreement Form

## Male Child

### Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the POMALYST REMS™ program, he will not be able to receive POMALYST. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of POMALYST and the Food and Drug Administration (FDA).

**I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with POMALYST (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the POMALYST REMS™ program.**

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature:
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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[Housing Unit Front Cover Flap]

((POMALYST REMS™ logo))

## **POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit**

[Housing Unit Front Cover]

### **Risks of POMALYST® (pomalidomide)**

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

((POMALYST logo))



[Housing Unit Spine]

**POMALYST Risk Evaluation and Mitigation Strategy (REMS)<sup>™</sup> program  
education and prescribing safety kit**

[Housing Unit Back Cover]

((POMALYST REMS™ logo))

## Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
  - Visiting **www.CelgeneRiskManagement.com**, or
  - Calling Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.

All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to POMALYST REMS™ Program.

5. The prescriber completes mandatory confidential survey and receives authorization number by:
  - Visiting **www.CelgeneRiskManagement.com**, or
  - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes POMALYST prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the POMALYST REMS™ procedures.

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

((Celgene logo))      ((POMALYST REMS™ logo))      ((POMALYST logo))

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Dear Prescriber:

## Enclosed are your POMALYST REMS™ program education materials

Celgene Corporation is pleased to provide you with the enclosed materials for use in the POMALYST REMS™ program.

Important Information about the POMALYST REMS™ program

- To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a restricted distribution program called "POMALYST REMS™."
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of pomalidomide in human semen. Male patients taking POMALYST should not donate sperm. Males receiving POMALYST must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with POMALYST REMS™ can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program

As a prescriber certified with the POMALYST REMS™ program, please review and familiarize yourself with the contents of the enclosed POMALYST REMS™ Kit:

### Prescriber Materials

- POMALYST REMS™ software and Installation Guide
- Prescriber Guide to POMALYST REMS™ Program
- POMALYST Full Prescribing Information

### Patient Materials (Patient Resource Pack)

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE



To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD

Chief Medical Officer

Enclosures

### **Risks of POMALYST® (pomalidomide)**

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

((Celgene logo))      ((POMALYST REMS™ logo))    ((POMALYST logo))

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## Pharmacy Guide to

((POMALYST REMS™ logo))

## Risk Evaluation and Mitigation Strategy (REMS)™ Program

### Important information about POMALYST® (pomalidomide) and the POMALYST REMS™ program

- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called “POMALYST REMS™”
- Only prescribers and pharmacists certified with the POMALYST REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program
- Dispensing pharmacists must be educated on the POMALYST REMS™ program and on dispensing procedures for POMALYST
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

((POMALYST logo))

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## Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide)

Dispensing pharmacies must be certified in the POMALYST REMS™ program with Celgene and must be educated in the following dispensing procedures.

### Step 1. Review incoming POMALYST prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
  - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
  - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

### Step 2. Counsel patient

- A. Make sure a **certified POMALYST REMS™** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST, make sure to document these experiences using acceptable documentation as noted on the checklist.
  - **Acceptable documentation examples:**
    1. Celgene Adverse Drug Event form and fax confirmation
    2. Pharmacy log

- D. Report adverse drug experiences that are suspected to be associated with the use of POMALYST to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

### **Step 3. Obtain confirmation number from Celgene Customer Care**

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **[www.CelgeneREMSPharmacyPortal.com](http://www.CelgeneREMSPharmacyPortal.com)**. Call your Celgene Account Manager to see if your pharmacy is eligible.
- Enter the pharmacy NABP number or DEA number
  - Enter the authorization number written on the prescription
  - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense POMALYST.

### **Step 4. Dispensing**

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.
- **Acceptable documentation examples:**
    1. Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
    2. Pharmacy log
- D. Document the dispense date and maintain a record on acceptable documentation.
- **Acceptable documentation examples:**
    1. Shipping receipt

2. Pharmacy dispensing log

- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
- F. A signature is required for all shipping and dispense if picked up by patient.

**Step 5. Perform drug accountability**

- A. Pharmacy shall keep an inventory log for POMALYST, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer POMALYST to another pharmacy without prior authorization from Celgene.
- C. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

## POMALYST Risk Evaluation and Mitigation Strategy (REMS)<sup>™</sup> Education and Counseling Checklist for Pharmacies

### *Ensure your patients know the risks*

Before you are able to fill a prescription for POMALYST<sup>®</sup> (pomalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off ([✓]) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

Be prepared to provide the following information for each checklist:

((IMAGE OF CHECKLIST))

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	

## Rules for dispensing and shipping

### *Making sure before you release POMALYST*

**DO NOT DISPENSE OR SHIP POMALYST TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:**

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing POMALYST prescription

**For further information about POMALYST, please refer to the full Prescribing Information, enclosed.**



## **Adverse drug experience reporting procedure for healthcare professionals**

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST® (pomalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods.

### **REPORTING TO CELGENE**

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

### **REPORTING TO THE FDA**

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

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## **Education and Counseling Checklist for Pharmacies**

### **POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety**

Authorization No.:      Confirmation No.:      Confirmation Date:

Pharmacy Name:

Pharmacy Address:

Counselor Name:      Work Phone:      Ext.:

Patient Name:      Date of Birth:

Risk Category:

## **Checklist for female patients of reproductive potential**

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

### **I COUNSELED ADULTS AND CHILDREN ON:**

☐ Potential embryo-fetal toxicity

☐ Not taking POMALYST® (pomalidomide) if pregnant or breastfeeding

- ☐ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth controls pills, hormonal patches, injections, vaginal rings, or implants), or partner’s vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
  
- ☐ Continuing to use at the **same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST **every time they have sex with a male**, or abstaining from sex with a male
  
- ☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

☐ The need to stop taking POMALYST right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately

☐ Possible side effects include deep vein thrombosis and pulmonary embolism

☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant

☐ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

☐ Not breaking, chewing, or opening POMALYST capsules

☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength \_\_\_\_\_ Number of Capsules Dispensed \_\_\_\_\_

**FEMALE CHILDREN (<18 YEARS OF AGE):**

☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

**Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)**

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

**I COUNSELED ADULTS AND CHILDREN ON:**

☐ Possible side effects include deep vein thrombosis and pulmonary embolism

☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant

☐ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

☐ Not breaking, chewing, or opening POMALYST capsules

☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength\_\_\_\_\_ Number of Capsules Dispensed\_\_\_\_\_

**FEMALE CHILDREN (<18 YEARS OF AGE):**

☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

☐ Parent or legal guardian must inform the child's doctor when the child begins menses

## Checklist for male patients

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

### I COUNSELED ADULTS AND CHILDREN ON:

☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)

☐ Female partners of males taking POMALYST® (pomalidomide) must call their healthcare provider right away if they get pregnant

☐ Possible side effects include deep vein thrombosis and pulmonary embolism

☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant

☐ Not donating blood or sperm while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST

☐ Not breaking, chewing, or opening POMALYST capsules

☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength\_\_\_\_\_ Numbers of Capsules Dispensed\_\_\_\_\_

### MALE CHILDREN (<18 YEARS OF AGE):

☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

**All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.**

**Counselor Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

For more information about POMALYST and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

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**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**

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REMS-POM13344



## Questions for POMALYST REMS™ Pharmacy Certification Quiz

1. Authorization numbers for females of reproductive potential are valid for up to \_\_\_\_ days:  
(Mandatory Question)
  - a. **7 days**
  - b. 10 days
  - c. 14 days
  - d. 28 days
2. It is not necessary to obtain a confirmation number to dispense. (Mandatory Question)
  - a. True
  - b. **False**
3. Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for each treatment. (Mandatory Question)
  - a. **True**
  - b. False
4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription. It is not necessary to complete the Education and Counseling Checklist.
  - a. True
  - b. **False**
5. According to the package insert's boxed warnings and warnings and precautions, venous thromboembolism have been reported in patients receiving POMALYST (Mandatory Question)
  - a. **True**
  - b. False
6. POMALYST can cause serious birth defects. (Mandatory Question)
  - a. **True**
  - b. False
7. What pregnancy precautions are required for a female of reproductive potential with respect to heterosexual sexual contact?
  - a. **Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy**
  - b. Abstain from having any heterosexual sexual contact only while taking therapy
  - c. After stopping therapy it is okay to get pregnant at any time
  - d. Use 2 forms of birth control 2 weeks before taking therapy
8. What precautions are required for a male with respect to sexual contact with his female partner of reproductive potential?
  - a. **Use of a latex or synthetic condom every time he has sexual intercourse with a female of reproductive potential during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy**

- b. Abstain from having any sexual contact with a females of reproductive potential only while taking therapy
  - c. Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped
  - d. Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms
- 9. For all Celgene REMS programs, female patients of reproductive potential must have a negative pregnancy test: *(Mandatory Question)*
  - a. Prior to initial prescription
  - b. Prior to subsequent prescription
  - c. **Prior to initial prescription and prior to subsequent prescription**
  - d. None of these
- 10. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to Celgene. *(Mandatory Question)*
  - a. **True**
  - b. False
- 11. The Medication Guide must be provided every time POMALYST is dispensed. *(Mandatory Question)*
  - a. **True**
  - b. False
- 12. A certified Celgene REMS pharmacy cannot dispense more than a \_\_\_\_\_ supply of POMALYST.
  - a. **28 day**
  - b. 3 month
  - c. 2 week
  - d. 1 year
- 13. Authorization numbers for patient risk categories other than females of reproductive potential are valid for up to \_\_\_\_\_ days. *(Mandatory Question)*
  - a. **30 days**
  - b. 10 days
  - c. 7 days
  - d. 28 days
- 14. A male patient can donate sperm at any time during therapy.
  - a. True
  - b. **False**

REMS-POM13252

((POMALYST REMS™ logo))

## **Patient Resource Pack**

### **POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program**

**The Patient Resource Pack contains:**

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.**

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## Patient Guide to

((Pomalyst REMS™ logo))

## Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of POMALYST® (pomalidomide)
  - Birth defects (deformed babies) or death of an unborn baby
  - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The POMALYST REMS™ Program
  - What females who can get pregnant need to know
    - Birth control options
  - What females who can not get pregnant need to know
  - What males need to know

((POMALYST logo))

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## **Risk of POMALYST® (pomalidomide)**

POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or death to unborn babies. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST.

POMALYST causes higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

## **What is the POMALYST REMS™ program?**

To avoid serious risks to unborn babies, POMALYST is only available under a restricted distribution program called the “POMALYST Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST. In order to receive POMALYST, patients must be enrolled in the POMALYST REMS™ program and agree to follow the requirements.

For more information about POMALYST and the POMALYST REMS™ program, visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

## What do all patients need to know about the POMALYST REMS™ program?

### General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- POMALYST® (pomalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle POMALYST capsules
- Keep POMALYST in a cool, dry place
- Do **not** donate blood while you are taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Unused POMALYST capsules should be returned for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you



## What do females who can get pregnant need to know about the POMALYST REMS™ program?

### A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you understand that POMALYST should not be used during pregnancy, and that you agree not to become pregnant while taking POMALYST
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking POMALYST
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for POMALYST, and again within 24 hours before you receive your first prescription for POMALYST. If you are pregnant, you cannot take POMALYST
- You will have pregnancy tests before starting POMALYST and while taking POMALYST, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

1. **Choose at least 1 highly effective method and at least 1 additional effective method of birth control.** Talk to your healthcare provider about the following acceptable birth control methods. See below.

## Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom + Diaphragm
Tubal ligation (having your tubes tied)	Cervical cap
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

## 2. Use the 2 methods of birth control at the same time

- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

**What do females who can get pregnant need to know about the POMALYST REMS™ program?  
(continued)**

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

**3. Unacceptable methods of birth control**

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield\*

**4. Take pregnancy tests**

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for POMALYST® (pomalidomide) and again within 24 hours before receiving your first prescription for POMALYST. Both pregnancy tests must have a negative result

\*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

**B. While taking POMALYST® (pomalidomide)**

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
  - Every week during the first 4 weeks of treatment, then
  - Every 4 weeks if your menstrual cycles are regular, or
  - Every 2 weeks if your cycles are irregular
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking POMALYST immediately and call your healthcare provider right away

**What do females who can get pregnant need to know about the POMALYST REMS™ program?  
(continued)**

- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking POMALYST® (pomalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking POMALYST
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

**C. After you have stopped taking POMALYST® (pomalidomide)**

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
  - For at least 4 weeks after stopping POMALYST, or
  - Do not have any sex with a male for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

## What do females who can not get pregnant need to know about the POMALYST REMS™ program?

### A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
  - You have been in natural menopause for at least 2 years, or
  - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting POMALYST
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

### B. While taking POMALYST

- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**

See also “General guidelines” on page 5 for requirements for all patients.

## What do males need to know about the POMALYST REMS™ program?

- You must use a latex or synthetic condom **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

### A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form. You must agree that while taking POMALYST you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing POMALYST, your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

### B. While taking POMALYST

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking POMALYST® (pomalidomide) (including during breaks [dose interruptions])
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**

### C. After you have stopped taking POMALYST

- For 4 weeks after receiving your last dose of POMALYST, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.





## **Mandatory confidential patient surveys**

As a patient who is enrolled in the POMALYST REMS™ program for POMALYST® (pomalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

### **Adult females who can get pregnant**

- Initial survey before first prescription
- Monthly

### **Adult females who can not get pregnant**

- Initial survey before first prescription
- Every six months

### **Female children**

- Initial survey before first prescription
- Monthly

### **Males**

- No initial survey
- Monthly

## **Mandatory confidential survey process**

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a POMALYST REMS™ certified pharmacy. The POMALYST REMS™ certified pharmacy will contact you to discuss your POMALYST® (pomalidomide) therapy. You will not receive your medication until you speak with the POMALYST REMS™ certified pharmacy

- For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

## **Warning to patients taking POMALYST® (pomalidomide)**

### **Attention females:**

Do **not** take POMALYST if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

### **Attention males:**

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

### **Attention all patients:**

You must **not** donate blood while taking POMALYST® (pomalidomide), during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

POMALYST must be kept out of the reach of children. Return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you.

[Back Cover]

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

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REMS-POM12146



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## REMS Patient Survey Reminder

Patient Name \_\_\_\_\_ Date Survey Available \_\_\_\_\_

Doctor Office Contact and Phone # \_\_\_\_\_

Product \_\_\_\_\_ Pharmacy Name \_\_\_\_\_

### Telephone Survey

OR

### Website Survey



From a touchtone  
phone dial **1-888-423-5436**

Para español, oprime el  
numero dos

to identify that you are a patient

to take a survey

Enter your 9-digit patient  
identification number (the number  
you provided during the enrollment  
process – for example your Social  
Security Number).

From the menu provided, select the drug that you  
have been prescribed



Your survey will then begin. Please answer all of the  
questions. Confirmation that the survey has been  
completed will be provided at the end of your survey.

Reference ID: 3627174

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Access the internet and type in the website address

**[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**

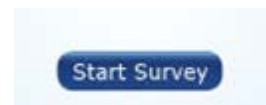
You are not required to have a User Name or Password  
to complete a survey. To take your survey, left click your  
mouse on the button



You will be asked for the following information. Please  
enter the information exactly as it was provided during  
your enrollment process

A form titled "Please enter your details in the form below to continue with the patient survey." It contains three input fields: "Patient Last Name:", "Patient First Name:", and "Patient Identification Number:". Below the last two fields is a note: "Social Security Number e.g. 123456789". At the bottom, it says "Please be sure to complete the survey in its entirety and upon completion send to Celgene."

After entering the information above, click



Survey questions will be displayed 1 per page. Please be sure  
to complete the survey in its entirety. A summary page  
displaying your survey answers will be displayed at the end of  
your survey. Upon completion, send the survey to Celgene by  
clicking


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1/13 REMS-GEN12169



## CelgeneRiskManagement.com


### Login Page




### Welcome to the Celgene REMS Program

To avoid embryo-fetal exposure, Risk Evaluation and Mitigation Strategy (REMS) programs are mandatory for the Celgene products THALOMID® (thalidomide), REVLIMID® (lenalidomide) and POMALYST® (pomalidomide). The THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program), REVLIMID REMS™ program (formerly known as the RevAssist® program), and POMALYST REMS™ program require prescribers and pharmacists to be certified and patients to enroll and comply with all of the requirements for each program.


If you would like to obtain more information about any of the Celgene REMS programs, please click on the program name below:



Visit [www.REVLIMIDREMS.com](http://www.REVLIMIDREMS.com),  
to learn more about the  
REVLIMID REMS™ program.



Visit [www.POMALYSTREMS.com](http://www.POMALYSTREMS.com),  
to learn more about the  
POMALYST REMS™ program.



Visit [www.THALOMIDREMS.com](http://www.THALOMIDREMS.com),  
to learn more about the  
THALOMID REMS™ program.

For prescribers, please enter your User Name and Password to manage your patients through a Celgene REMS program. If you do not have an online account, select Create User Account to establish an account. Patients currently enrolled in a Celgene REMS program are not required to create an online account to complete a survey. Please select Patient Surveys and enter the information requested to begin a survey.

To login to your account:

User Name:

Password:

[Forgot Password? >](#)

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## Home Page (after prescriber login)

The screenshot shows the Celgene Home Page after a prescriber login. The page has a dark blue header with the text "first last" on the left and three buttons: "Home", "Help", and "Logout" on the right. The main content area is light blue and features the Celgene logo in the top left corner. Below the logo, there is a paragraph of text: "Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription." This text is followed by three columns, each representing a different REMS program. The first column is for REVLMID REMS™ (formerly known as the RevAssist® program), the second is for POMALYST REMS™, and the third is for THALOMID REMS™ (formerly known as the S.T.E.P.S.® program). Each column contains a button with the product name and a link to the full prescribing information, which includes Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS. At the bottom of the main content area, there is a paragraph of text: "The Prescriber Dashboard is an optional resource that displays the status of patients under your care for a specific Celgene REMS program. A patient search function is also included to access detailed patient history information. Select the 'Manage My Account' button to view your Celgene REMS online account information." Below this text are two buttons: "Prescriber Dashboard" and "Manage My Account". The footer of the page contains links for "Contact Us", "Terms of Use", and "Privacy Policy", along with the copyright notice "©2005-2013, Celgene Corporation".

first last

Home Help Logout

**Celgene**

Home

Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription.

For REVLMID REMS™  
(formerly known as the RevAssist® program)

**RevlimidREMS™**

Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For POMALYST REMS™

**PomalystREMS™**

Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For THALOMID REMS™  
(formerly known as the S.T.E.P.S.® program)

**THALOMIDREMS™**

Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

The Prescriber Dashboard is an optional resource that displays the status of patients under your care for a specific Celgene REMS program. A patient search function is also included to access detailed patient history information.

Select the "Manage My Account" button to view your Celgene REMS online account information.


Prescriber Dashboard Manage My Account

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## Pomalyst REMS module










# Pomalyst REMS™

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

## Welcome to the POMALYST REMS™ program

POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

### Important information about POMALYST and the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program

- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called "POMALYST REMS™"
- Only prescribers and pharmacies certified by the POMALYST REMS™ program can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program


The goals of the POMALYST risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to POMALYST
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for POMALYST

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

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### About the POMALYST REMS™ program

POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called "POMALYST Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST in the POMALYST REMS™ program.

In order to receive POMALYST, all patients must be enrolled in the POMALYST REMS™ program and agree to comply with the requirements of the POMALYST REMS™ program.

#### Key points of the POMALYST REMS™ program

##### Prescriber

- The prescriber enrolls and becomes certified with Celgene for the POMALYST REMS™ program
- The prescriber counsels patient on benefits and risks of POMALYST
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends POMALYST prescription to a certified pharmacy

##### Pharmacy

- The pharmacy certifies with Celgene for the POMALYST REMS™ program
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Field

### Prescriber Resources

POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

#### Enrolling in POMALYST REMS™

In order to prescribe POMALYST, you must enroll in the POMALYST REMS™ program and agree to follow the requirements of the program. You can enroll by visiting [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com), a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to Celgene Customer Care at 1-888-432-9325.

Prescriber Enrollment Form 

#### Prescribing POMALYST for your patients


In order to receive POMALYST, your patients must also be enrolled in the POMALYST REMS™ program. You can enroll your patients, and fill out a prescription form using [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com). You and your patients can also complete your mandatory confidential surveys there.

Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.

Enroll Your Patients at  
[CelgeneRiskManagement.com](http://CelgeneRiskManagement.com)

Desktop Software  
Installation

Installation  
User Guide 

Patient Prescription Form 

#### Learning more about POMALYST REMS™

For a complete overview of the POMALYST REMS™ program, and a guide to the POMALYST REMS™ process, please see the educational materials below.

Prescriber Guide to  
POMALYST REMS™ Program 

POMALYST REMS™  
At-A-Glance 

Full Prescribing Information 

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods:

#### REPORTING TO CELGENE

Email: [drugsafety@celgene.com](mailto:drugsafety@celgene.com)

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or  
1-888-423-5436 (Celgene Customer Care Center)

Fax: 1-908-673-9115

Mail to: Global Drug Safety & Risk Management  
Celgene Corporation  
300 Connell Dr.  
Suite 6000  
Berkeley Heights, NJ 07922

#### REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Telephone: 1-800-332-1088

Fax: 1-800-332-0178

Mail to: MedWatch  
5600 Fishers Lane  
Rockville, MD 20852-9787

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

### Patient Resources

POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

#### What you need to know about the POMALYST REMS™ program

Your doctor will enroll you in the POMALYST REMS™ program so that you can receive your medication. Use the materials below to learn more about the POMALYST REMS™ program, and what you need to do.

Patient Guide to POMALYST REMS™ Program 

Patient Survey Reminder Card 

Patient Medication Guide 

Visit Planned Parenthood site for Emergency Contraception Brochure

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

## Pharmacist Resources


POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

### POMALYST REMS™ information for certified pharmacies

POMALYST is only dispensed from POMALYST REMS™ program certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-423-5436.

As a POMALYST REMS™ certified pharmacy, you must follow the requirements of the POMALYST REMS™ program. You may download a guide to the program, a checklist for counseling patients, and the full prescribing information below.

Pharmacy Guide to POMALYST REMS™ Program 

Education and Counseling Checklist for Pharmacies 

Full Prescribing Information 

### The Celgene REMS Pharmacy Portal

In addition to calling the Celgene Customer Care Center to obtain a confirmation number for a prescription, eligible pharmacies can obtain confirmation numbers using the Celgene REMS Pharmacy Portal at [CelgeneREMSPharmacyPortal.com](http://CelgeneREMSPharmacyPortal.com). Contact your Celgene Account Manager to see if your pharmacy is eligible.

Celgene REMS Pharmacy Portal

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods:

#### REPORTING TO CELGENE

**Email:** [drugsafety@celgene.com](mailto:drugsafety@celgene.com)

**Telephone:** 1-800-673-9667

**Toll-free:** 1-800-640-7854 (Global Drug Safety & Risk Management) or  
1-888-423-5436 (Celgene Customer Care Center)

**Fax:** 1-800-673-9116

**Mail to:** Global Drug Safety & Risk Management  
Celgene Corporation  
300 Connett Dr.  
Suite 6000  
Berkeley Heights, NJ 07922

#### REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

**Online:** <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

**Telephone:** 1-800-332-1088

**Fax:** 1-800-332-0178

**Mail to:** MedWatch  
5600 Fishers Lane  
Rockville, MD 20852-9787

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

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# Prescriber Guide to Pomalyst REMS™ Risk Evaluation and Mitigation Strategy (REMS)™ Program

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**Due to its structural similarity to thalidomide, a known teratogen, POMALYST® (pomalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program.**

This guide contains important information for prescribers about:

- The risks of POMALYST, including a boxed warning for
  - Embryo-fetal toxicity
  - Venous thromboembolism
- The POMALYST REMS™ program
  - Prescriber Certification
  - Patient Enrollment
  - Contraceptive Requirements and Counseling for Patients
  - Initial and Subsequent Prescription Requirements

## **POMALYST REMS™ Resources for Prescribers Include:**

- Prescriber Guide to POMALYST REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for POMALYST



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About POMALYST® (pomalidomide)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

Risks of POMALYST

**POMALYST has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism.**

**Due to the fact that it is an analogue of thalidomide, a known teratogen,** POMALYST is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST if they take adequate precautions to avoid pregnancy.

Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE) occurred in patients with multiple myeloma treated with pomalidomide. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient’s underlying risk factors.

# The POMALYST REMS™ program

To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a restricted distribution program called “POMALYST Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST in the POMALYST REMS™ program.

In order to receive POMALYST, all patients must be enrolled in POMALYST REMS™ and agree to comply with the requirements of the POMALYST REMS™ program. Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

## Key points of the POMALYST REMS™ program

### Prescriber

- The prescriber enrolls and becomes certified with Celgene for the POMALYST REMS™ program
- The prescriber counsels patient on benefits and risks of POMALYST
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends POMALYST prescription to certified pharmacy

### Pharmacy

- The pharmacy certifies with Celgene for POMALYST REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

# POMALYST REMS™ patient enrollment

- Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with POMALYST REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the POMALYST® (pomalidomide) Patient-Physician Agreement Form in the language of their choice

## Help Ensure Timely Processing of Each Prescription

### Fill Out Form as Directed

- Write only in the designated areas on the POMALYST® (pomalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

### Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

### Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

### Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form

# POMALYST REMS™ patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient’s behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber’s letterhead, must be submitted to the Celgene Customer Care Center, along with the POMALYST® (pomalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative’s relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient’s compliance with the POMALYST REMS™ program and is authorized to consent to treatment with POMALYST on behalf of the patient

## Send in Completed Forms

- Send the completed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the POMALYST® (pomalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

**Note:** If therapy with POMALYST is discontinued for 12 consecutive months, the patient must enroll again in the POMALYST REMS™ program. Follow the above procedures to re-enroll the patient.

# Initial prescription requirements

## ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with POMALYST® (pomalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with POMALYST
- Provide counseling not to share POMALYST capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of POMALYST, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the POMALYST REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open POMALYST capsules
- Instruct patients to return unused POMALYST capsules for disposal to Celgene or to their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them

## FEMALE PATIENTS

### Determine if female patient is of reproductive potential

#### Two categories:

#### 1. Females of Reproductive Potential

- All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category

#### 2. Females Not of Reproductive Potential

- Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for POMALYST® (pomalidomide) and again within 24 hours prior to writing an initial prescription for POMALYST even if continuous abstinence is the chosen method of birth control
  - The pregnancy test must be sensitive to at least 50 mIU/mL
  - Pregnancy testing should occur weekly during the first 4 weeks of use
  - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
  - If a patient misses her period or if there is any abnormality in menstrual bleeding, POMALYST should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, POMALYST must be immediately discontinued.** Any suspected embryo-fetal exposure to POMALYST must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with POMALYST

Initial prescription requirements (continued)

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
<ul style="list-style-type: none"><li>• Intrauterine device (IUD)</li><li>• Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)</li><li>• Tubal ligation (having your tubes tied)</li><li>• Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)</li></ul>	<div>+</div> <ul style="list-style-type: none"><li>• Male latex or synthetic condom</li><li>• Diaphragm</li><li>• Cervical cap</li></ul>

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

- **Unacceptable forms of contraception:**
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield\*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

\*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.



# Initial prescription requirements (continued)

## 2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before POMALYST® (pomalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

## MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking POMALYST therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of POMALYST

# Initial mandatory confidential survey

## Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

## Males

- Males do not need to take the initial survey

## Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or by calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
  - Prescriber’s identification number
  - Patient’s identification number
  - Date and result of patient’s pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
  - Average daily dose
  - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

## ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a POMALYST REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

## Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for POMALYST® (pomalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

### FEMALE PATIENTS

- Provide counseling as outlined in the “FEMALE PATIENTS” section on pages 7-10
- Follow pregnancy test requirements as outlined in the “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
  - Before prescription is obtained
  - Monthly
    - Adult females of reproductive potential
    - All female children
  - Every 6 months
    - Adult females not of reproductive potential

### MALE PATIENTS

- Provide patient counseling as outlined in the “MALE PATIENTS” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
  - Males do not complete an initial survey

## After the last dose of POMALYST® (pomalidomide)

After patients have stopped taking POMALYST, they must do the following:

### ALL PATIENTS

- Must not share POMALYST capsules—especially with females of reproductive potential
- Must return any unused POMALYST capsules for disposal to Celgene or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Must not donate blood for 4 weeks after stopping POMALYST

### FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping POMALYST by using the appropriate contraceptives each time engaging in sexual activity with a male

### MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping POMALYST
- Must not donate sperm for 4 weeks after stopping POMALYST



# Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
  - POMALYST® (pomalidomide) Patient-Physician Agreement Forms
  - Patient Guide to POMALYST REMS™ Program
  - Mandatory confidential survey forms

Available languages:			
Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- POMALYST® (pomalidomide) Patient-Physician Agreement Forms, Patient Guide to POMALYST REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name  
Identification Number  
Full Address  
Fax Number

Patient's:

Name  
Full Address  
Phone Number  
Date of Birth  
Identification Number  
Diagnosis (most recent version of ICD code)

# Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST® (pomalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods.

## REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

## REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**



**Pomalyst REMS™**



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.



# REMS Patient Survey Reminder

Patient Name \_\_\_\_\_ Date Survey Available \_\_\_\_\_

Doctor Office Contact and Phone # \_\_\_\_\_

Product \_\_\_\_\_ Pharmacy Name \_\_\_\_\_

## Telephone Survey

OR

## Website Survey

1	2	3
4	5	6
7	8	9
*	0	#

From a touchtone  
phone dial  
**1-888-423-5436**

Press

**2**

Para español, oprime  
el numero dos

Press

**1**

to identify that you are  
a patient

Press

**1**

to take a survey

1	2	3
4	5	6
7	8	9
*	0	#

Enter your 9-digit patient  
identification number (the  
number you provided during  
the enrollment process – for  
example your Social Security  
Number).

From the menu provided, select the drug that  
you have been prescribed.

Press

**1**

OR

Press

**2**

OR

Press

**3**

Your survey will then begin. Please answer all  
of the questions. Confirmation that the survey  
has been completed will be provided at the  
end of your survey.

Access the internet and type in the website address  
**[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**

You are not required to have a User Name or Password  
to complete a survey. To take your survey, left click your  
mouse on the button

Patient Surveys

You will be asked for the following information. Please  
enter the information exactly as it was provided during  
your enrollment process

Please enter your details in the form below to continue with the patient survey.

\* Patient Last Name:

\* Patient First Name:

\* Patient Identification Number:

Social Security Number e.g. 123456789

Please be sure to complete the survey in its entirety and upon completion send to Celgene.

After entering the information above, click

Start Survey

Survey questions will be displayed 1 per page. Please be  
sure to complete the survey in its entirety. A summary  
page displaying your survey answers will be displayed at  
the end of your survey. Upon completion, send the survey  
to Celgene by clicking

Send to Celgene

# Pomalyst REMS™

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Dear Prescriber:

## Enclosed are your POMALYST REMS™ program education materials

Celgene Corporation is pleased to provide you with the enclosed materials for use in the POMALYST REMS™ program.

Important Information about the POMALYST REMS™ program

- To avoid embryo-fetal exposure, POMALYST® (pomalidomide) is only available under a special restricted distribution program called "POMALYST REMS™"
- Pomalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with pomalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of pomalidomide in human semen. Male patients taking POMALYST should not donate sperm. Males receiving POMALYST must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with POMALYST REMS™ can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program

As a prescriber certified in the POMALYST REMS™ program, please review and familiarize yourself with the contents of the enclosed POMALYST REMS™ Kit:

### Prescriber Materials

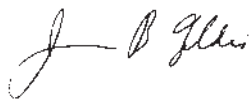
- POMALYST REMS™ software and Installation Guide
- Prescriber Guide to POMALYST REMS™ Program
- POMALYST Full Prescribing Information

### Patient Materials (Patient Resource Pack)

- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,



Jerome B. Zeldis, MD, PhD  
Chief Medical Officer

Enclosures

## Risks of POMALYST® (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**



**Pomalyst REMS™**



POMALYST® is a registered trademark of Celgene Corporation. POMALYST REMS™ is a trademark of Celgene Corporation.

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1/13

REMS-POM12143

Reference ID: 3627174

# Pomalyst REMS™

## *At-A-Glance*

### **Important information about POMALYST® (pomalidomide) and the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program**

- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called “POMALYST REMS™”
- Only prescribers and pharmacies certified by the POMALYST REMS™ program can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

For more information about POMALYST and the POMALYST REMS™ program, please visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**



**Pomalyst REMS™**



## Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for POMALYST® (pomalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Obtain, review, and complete the POMALYST® (pomalidomide) Patient-Physician Agreement Form online at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
  - **Males (adults and children)**
  - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
  - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed POMALYST® (pomalidomide) Patient-Physician Agreement Form online through [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
  - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
  - You will need to enter the following information:
    - Prescriber's identification number
    - Patient's identification number
    - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
    - Average daily dose
    - Total number of days supplied (cannot exceed 28 days)

7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
8. Send the prescription to a certified pharmacy.

## Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open POMALYST capsules.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
  - Monthly:
    - **Males (adults and children)**
    - **Females of reproductive potential (adults and children)**
    - **Female children not of reproductive potential**
  - Every 6 months:
    - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
  - You will need to enter the following information:
    - Prescriber's identification number
    - Patient's identification number
    - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
    - Average daily dose
    - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.



# Pomalyst REMS™

## Prescriber Enrollment Form

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All prescribers must be certified to prescribe POMALYST® (pomalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for POMALYST REMS™ certification.
2. Agree to steps on the following page that must be followed with every patient.

To submit this form electronically, please go to **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that must be followed with every patient.



# POMALYST REMS™ Prescriber Enrollment Form

When prescribing POMALYST® (pomalidomide), I agree to:

- Provide patient counseling on the benefits and risks of POMALYST therapy, including Boxed Warnings
- Submit a completed POMALYST® (pomalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during POMALYST treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed POMALYST immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a POMALYST REMS™ certified pharmacy to fill the prescription
- Return to Celgene all POMALYST capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all POMALYST capsules to Celgene Corporation or their POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to them
- Re-enroll patients in the POMALYST REMS™ program if POMALYST is required and previous therapy with POMALYST has been discontinued for 12 consecutive months

Please fill out the spaces below completely.

Prescriber Name \_\_\_\_\_

Degree: MD/DO/PA/NP/Fellow/Medical Resident

Specialty \_\_\_\_\_

Prescriber Identification Number (eg, DEA Number, Social Security Number, NPI Number, etc.) \_\_\_\_\_

Please indicate which office(s) will receive POMALYST REMS™ materials and updates:

☐ Primary Office Name \_\_\_\_\_

Attention \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_

Phone \_\_\_\_\_ Ext. \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

☐ Secondary Office Name \_\_\_\_\_

Attention \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_

Phone \_\_\_\_\_ Ext. \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

I understand that if I fail to comply with all requirements of the POMALYST REMS™ program, my prescriptions for POMALYST® (pomalidomide) will not be honored at certified pharmacies.

Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: 1-888-423-5436 Fax: 1-888-432-9325 [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)



Pomalyst REMS™



## Pomalyst REMS<sup>™</sup>

POMALYST Risk Evaluation and Mitigation Strategy (REMS)<sup>™</sup> program  
education and prescribing safety kit

### Risks of POMALYST<sup>®</sup> (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID<sup>®</sup>). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.



## Risks of POMALYST® (pomalidomide)

- POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or embryo-fetal death. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST
- POMALYST causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

POMALYST is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.





# Pomalyst REMS™

## Prescriber quick reference guide

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1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
  - Visiting **www.CelgeneRiskManagement.com**, or
  - Calling Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.  
All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to POMALYST REMS™ Program.
5. The prescriber completes mandatory confidential survey and receives authorization number by:
  - Visiting **www.CelgeneRiskManagement.com**, or
  - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes POMALYST prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the POMALYST REMS™ procedures.

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**



Pomalyst REMS™



## Pharmacy Guide to

# Pomalyst REMS™

## Risk Evaluation and Mitigation Strategy (REMS)™ Program

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### Important information about POMALYST® (pomalidomide) and the POMALYST REMS™ program

- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called “POMALYST REMS™”
- Only prescribers and pharmacies certified with the POMALYST REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program
- Dispensing pharmacists must be educated on the POMALYST REMS™ program and on dispensing procedures for POMALYST
- Information about POMALYST and the POMALYST REMS™ program can be obtained by visiting **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**



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Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide)

Dispensing pharmacies must be certified in the POMALYST REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming POMALYST prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
  - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
  - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patient

- A. Make sure a **certified POMALYST REMS™** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST, make sure to document these experiences using acceptable documentation as noted on the checklist.
  - **Acceptable documentation examples:**
    - 1. Celgene Adverse Drug Event form and fax confirmation
    - 2. Pharmacy log
- D. Report adverse drug experiences that are suspected to be associated with the use of POMALYST to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

# Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide) (continued)

## Step 3. Obtain confirmation number from Celgene Customer Care

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **www.CelgeneREMSPharmacyPortal.com**. Call your Celgene Account Manager to see if your pharmacy is eligible.
  - Enter the pharmacy NABP number or DEA number
  - Enter the authorization number written on the prescription
  - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense POMALYST.

## Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.
  - **Acceptable documentation examples:**
    1. Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
    2. Pharmacy log

# Guidelines for ordering, counseling, and dispensing POMALYST® (pomalidomide) (continued)

- D. Document the dispense date and maintain a record on acceptable documentation.

- **Acceptable documentation examples:**

1. Shipping receipt
2. Pharmacy dispensing log

- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
- F. A signature is required for all shipping and dispense if picked up by patient.

## Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for POMALYST, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer POMALYST to another pharmacy without prior authorization from Celgene.
- C. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.



# POMALYST Risk Evaluation and Mitigation Strategy (REMS)<sup>™</sup> Education and Counseling Checklist for Pharmacies

## Ensure your patients know the risks

Before you are able to fill a prescription for POMALYST<sup>®</sup> (pomalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off (✓) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.



Be prepared to provide the following information for each checklist:

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	

## Rules for dispensing and shipping

### Making sure before you release POMALYST

#### DO NOT DISPENSE OR SHIP POMALYST TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing POMALYST prescription

For further information about POMALYST, please refer to the full Prescribing Information, enclosed.

# Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of POMALYST<sup>®</sup> (pomalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods.

### REPORTING TO CELGENE

- Email: [drugsafety@celgene.com](mailto:drugsafety@celgene.com)
- Telephone: 1-908-673-9667
- Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
- Fax: 1-908-673-9115
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

### REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
- Telephone: 1-800-332-1088
- Fax: 1-800-332-0178
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.**



**Pomalyst REMS™**



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REMS-POM13280

# Pomalyst REMS™

## Education and Counseling Checklist for Pharmacies

### POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety

Authorization No.: \_\_\_\_\_ Confirmation No.: \_\_\_\_\_ Confirmation Date: \_\_\_\_\_  
Pharmacy Name: \_\_\_\_\_  
Pharmacy Address: \_\_\_\_\_  
Counselor Name: \_\_\_\_\_ Work Phone: \_\_\_\_\_ Ext.: \_\_\_\_\_  
Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Risk Category: \_\_\_\_\_

#### Checklist for female patients of reproductive potential

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

##### I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity
- ☐ Not taking POMALYST® (pomalidomide) if pregnant or breastfeeding
- ☐ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- ☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST **every time they have sex with a male**, or abstaining from sex with a male
- ☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- ☐ The need to stop taking POMALYST right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ☐ Not breaking, chewing, or opening POMALYST capsules
- ☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength \_\_\_\_\_

Number of Capsules Dispensed \_\_\_\_\_

##### FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

#### Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

##### I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ☐ Not breaking, chewing, or opening POMALYST capsules
- ☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength \_\_\_\_\_

Number of Capsules Dispensed \_\_\_\_\_

##### FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance
- ☐ Parent or legal guardian must inform the child's doctor when the child begins menses

## Checklist for male patients

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

### I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)
- ☐ Female partners of males taking POMALYST® (pomalidomide) must call their healthcare provider right away if they get pregnant
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood or sperm while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ☐ Not breaking, chewing, or opening POMALYST capsules
- ☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength \_\_\_\_\_

Number of Capsules Dispensed \_\_\_\_\_

### MALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

**All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.**

Counselor Signature: \_\_\_\_\_ Date: \_\_\_\_\_

For more information about POMALYST and the POMALYST REMS™ program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center at 1-888-423-5436.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

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**Pomalyst REMS™**



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REMS-POM13344

# **Celgene REMS Programs Pharmacy Training: POMALYST REMS™**

## **Section 1: What Is a REMS?**



## In this section



- What is a REMS?
- Celgene REMS programs
- Pharmacy staff knowledge check

# What is a REMS?



- REMS stands for **Risk Evaluation and Mitigation Strategies**
- REMS programs are mandated by the **US Food and Drug Administration (FDA)**
- According to the FDA, a REMS program is:
  - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

# Celgene REMS programs



- Celgene has REMS programs for THALOMID® (thalidomide), REVLIMID® (lenalidomide), and POMALYST® (pomalidomide)
- If these treatments are used during pregnancy, they can cause serious birth defects or embryo-fetal death
- The goals of these REMS programs are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment



## Celgene REMS programs (continued)



For more information on Celgene REMS programs:

- Call Celgene Customer Care at 1-888-423-5436
- Visit the specific product website

### Did you know?

Celgene Customer Care has Compliance Specialists to educate and train pharmacy staff on Celgene REMS program guidelines and compliance.

# Pharmacy staff knowledge check



- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

**Correct Answer: A. True**

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

## Pharmacy staff knowledge check (continued)



- Who mandates REMS programs?
  - A. Celgene
  - B. The FDA
  - C. The EPA

**Correct Answer: B. The FDA**

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

## Pharmacy staff knowledge check (continued)



- Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment.
  - A. True
  - B. False

**Correct Answer: A. True**

- The goals of the Celgene REMS programs are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

# **Celgene REMS Programs Pharmacy Training: POMALYST REMS™**

## **Section 2: Program Requirements for Patients and Prescribers**

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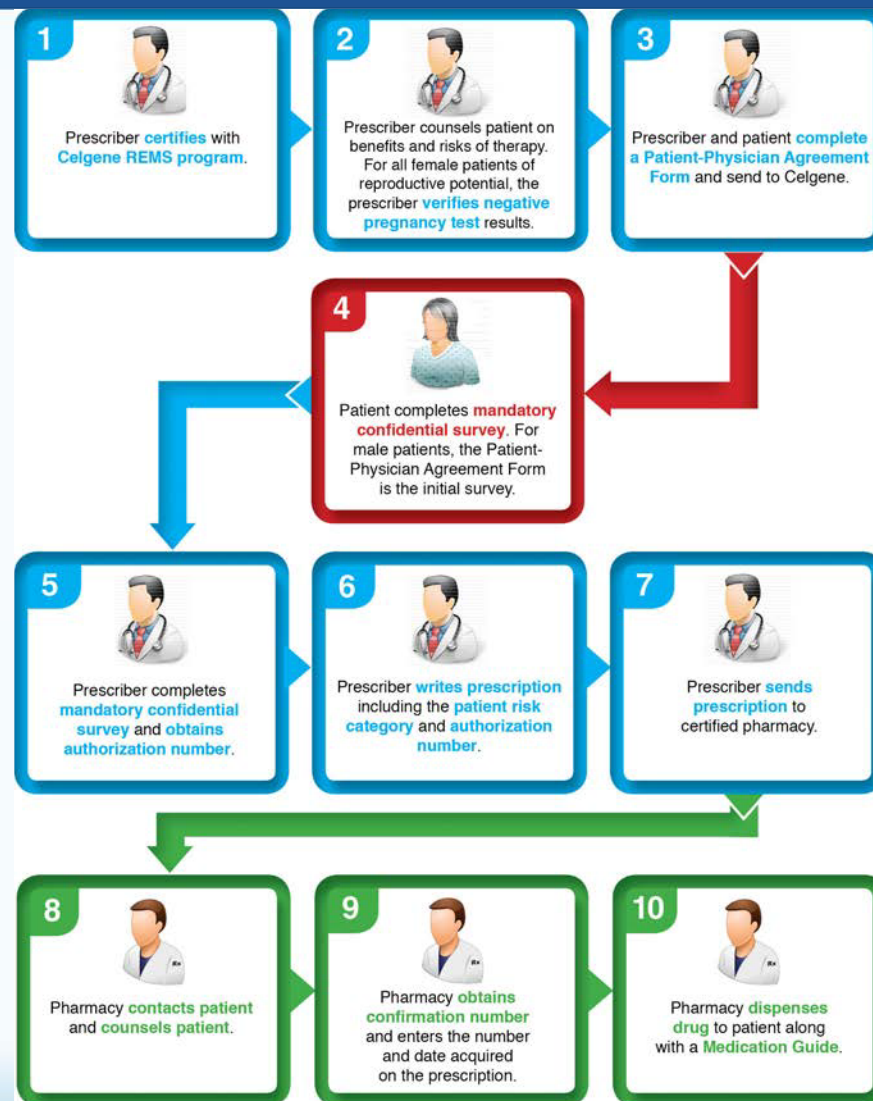


## In this section



- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

# Celgene REMS program overview



# Certification and enrollment requirements for prescribers and patients



- Prescribers must be certified with the Celgene REMS program in order to prescribe a product with a REMS program for a patient
  - Prescribers must complete the REMS program enrollment and agree to comply with the program requirements
- Prescribers are required to enroll patients in a specific Celgene REMS program before starting a patient on a therapy with a REMS
  - Patients must enroll in the REMS program and agree to comply with the program requirements



# Patient risk categories



- There are 6 different patient risk categories for patients enrolled in Celgene REMS programs:
  - Adult female of reproductive potential
  - Female child of reproductive potential
  - Adult female not of reproductive potential
  - Female child not of reproductive potential
  - Adult male
  - Male child

# Definition of females of reproductive potential



**Females of reproductive potential** include all females who:

- Are menstruating
- Are amenorrheic from previous medical treatments
- Are under 50 years of age
- Are perimenopausal
- Do not qualify for the females not of reproductive potential category

The risk categories for **females of reproductive potential** are:

- Adult female of reproductive potential
- Female child of reproductive potential

# Definition of females not of reproductive potential



**Females not of reproductive potential** include females who:

- Have been in natural menopause for at least 24 consecutive months
- Have had a hysterectomy and/or bilateral oophorectomy
- Have not started menstruating

The risk categories for **females not of reproductive potential** are:

- Adult female not of reproductive potential
- Female child not of reproductive potential

# Definition of males



**Males** include adults and children (under 18 years of age)

The risk categories for **males** are:

- Adult Male
- Male Child

# Contraception requirements: Females of reproductive potential



- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time **at least 1 highly effective method** and **at least 1 additional method** of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

## Highly effective methods

Tubal ligation

Intrauterine device (IUD)

Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Partner's vasectomy

## Additional effective methods

Male latex or synthetic condom

Diaphragm

Cervical cap

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

# Contraception requirements: Females of reproductive potential (continued)



- **Unacceptable contraception methods:**
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield
    - A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

# Contraception requirements: Males



- Male patients must use a latex or synthetic condom:
  - Every time they have sexual intercourse with a female of reproductive potential
  - Even if they have undergone a successful vasectomy
  - During therapy (including dose interruptions)
  - For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

# Pregnancy test requirements



- For females of reproductive potential, prescriber must obtain a negative pregnancy test:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription
  - The pregnancy test must be sensitive to at least 50 mIU/mL
- Subsequent pregnancy testing should occur:
  - Weekly during the first 4 weeks of use, then
  - Every 4 weeks if patient has regular menses or no menses, or
  - Every 2 weeks if irregular menses



## Pregnancy test requirements (continued)



### If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to Celgene Global Drug Safety and reported to the FDA
  - Celgene Global Drug Safety: 1-800-640-7854
  - FDA MedWatch number: 1-800-332-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

# Mandatory confidential surveys



- All patients must complete brief mandatory confidential surveys in order to obtain treatment
  - Surveys can be completed via [CelgeneRiskManagement.com](http://CelgeneRiskManagement.com) or by calling Celgene Customer Care at 1-888-423-5436

**Patient Mandatory Confidential Survey Schedule for Adults and Children**

Risk category	Initial Prescription	Subsequent Prescriptions
Females of reproductive potential	Complete appropriate survey	Monthly survey
Females not of reproductive potential	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

# Pharmacy staff knowledge check



- How many patient risk categories are there in the Celgene REMS programs?
  - A. 3
  - B. 5
  - C. 6

**Correct Answer: C. 6**

Celgene REMS program patient risk categories	
Adult	Child (under 18)
Adult female of reproductive potential	Female child of reproductive potential
Adult female not of reproductive potential	Female child not of reproductive potential
Adult male	Male child

## Pharmacy staff knowledge check (continued)



- For all Celgene REMS products, female patients of reproductive potential must take a pregnancy test:
  - A. 10-14 days before first prescription
  - B. Within 24 hours before first prescription
  - C. 10-14 days and within 24 hours before first prescription

**Correct Answer:**

**C. 10-14 days and within 24 hours before first prescription**

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females of reproductive potential:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription

## Pharmacy staff knowledge check (continued)



- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

**Correct Answer: B. IUD**

Highly effective methods	Additional effective methods
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	

# **Celgene REMS Programs Pharmacy Training: POMALYST REMS™**

## Section 3: Program Requirements for Pharmacies

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## In this section



- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

# Training and certification requirements



- Celgene REMS program certified counselors must:
  - Be licensed healthcare professionals
  - Complete the Celgene-sponsored training on all required modules **annually** and pass certification exam **with 100% accuracy**
  - Educate patient by telephone or in person before treatment can be dispensed
  - Understand and counsel patients on the potential for birth defects or death to an unborn baby
  - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
  - Be educated on the guidelines for dispensing



# Pharmacy compliance



- Pharmacy manager responsibilities
  - Educate all staff regarding dispensing guidelines
    - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
  - Make sure counselors are registered and certified in ComplianceWire® and advise Celgene of inactive counselors
  - Complete and return all documentation that pertains to non-compliance

**Did you know?** Pharmacy managers can call Celgene Customer Care at **1-888-423-5436** with questions. Ask for Risk Compliance.

# Pharmacy compliance (continued)



- Pharmacy deviations
  - The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
  - Celgene will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
  - If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

## Pharmacy compliance (continued)



- A High Risk Deviation is:
  - Any action taken by the pharmacy that is inconsistent or non-compliant with the Celgene REMS program that increases the risk of embryo-fetal exposure
  - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Celgene REMS program requirements
- If there are 3 High Risk Deviations within 1 year, the pharmacy will be deactivated and will no longer be permitted to dispense product

# Pharmacy staff knowledge check



- Celgene REMS program certified counselors must complete the Celgene-sponsored training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

**Correct Answer: A. Annually**

- Counselors must complete the Celgene-sponsored training annually

## Pharmacy staff knowledge check (continued)



- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

**Correct Answer: A. 100%**

- Counselors must pass the certification exam with 100% accuracy

## Pharmacy staff knowledge check (continued)



- Celgene may deactivate pharmacies for deviations.
  - A. True
  - B. False

**Correct Answer: A. True**

- The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

# **Celgene REMS Programs Pharmacy Training: POMALYST REMS™**

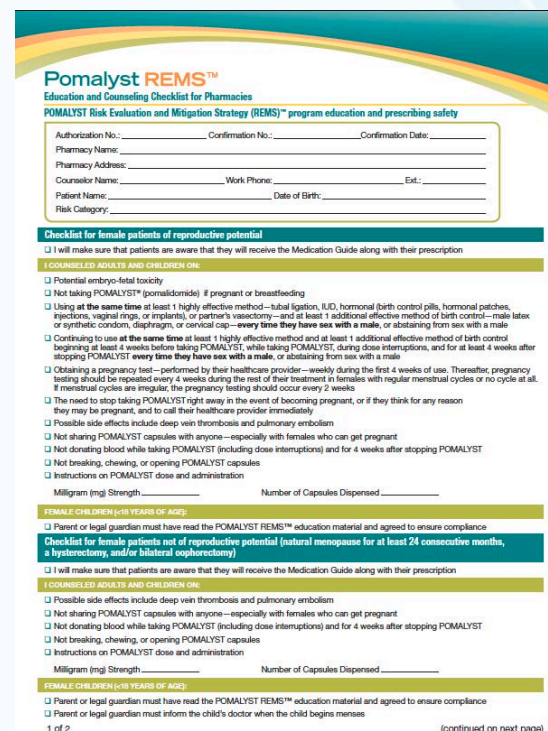
## Section 4: Guidelines for Counseling

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## In this section

- Counseling for female patients of reproductive potential
- Counseling for female patients not of reproductive potential
- Counseling for male patients
- Additional counseling for all patients taking POMALYST® (pomalidomide)
- Pharmacy staff knowledge check



**Pomalyst REMS™**  
Education and Counseling Checklist for Pharmacies  
POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety

Authorization No.: \_\_\_\_\_ Confirmation No.: \_\_\_\_\_ Confirmation Date: \_\_\_\_\_  
Pharmacy Name: \_\_\_\_\_  
Pharmacy Address: \_\_\_\_\_  
Counselor Name: \_\_\_\_\_ Work Phone: \_\_\_\_\_ Ext.: \_\_\_\_\_  
Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Risk Category: \_\_\_\_\_

**Checklist for female patients of reproductive potential**

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

**COUNSELED ADULTS AND CHILDREN ON:**

- ☐ Potential embryo-fetal toxicity
- ☐ Not taking POMALYST™ (pomalidomide) if pregnant or breastfeeding
- ☐ Using at the same time at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—every time they have sex with a male, or abstaining from sex with a male
- ☐ Continuing to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking POMALYST, while taking POMALYST, during dose interruptions, and for at least 4 weeks after stopping POMALYST every time they have sex with a male, or abstaining from sex with a male
- ☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- ☐ The need to stop taking POMALYST right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ☐ Not breaking, chewing, or opening POMALYST capsules
- ☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength: \_\_\_\_\_ Number of Capsules Dispensed: \_\_\_\_\_

**FEMALE CHILDREN (≤18 YEARS OF AGE):**

- ☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance

**(Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy))**

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

**COUNSELED ADULTS AND CHILDREN ON:**

- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing POMALYST capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking POMALYST (including dose interruptions) and for 4 weeks after stopping POMALYST
- ☐ Not breaking, chewing, or opening POMALYST capsules
- ☐ Instructions on POMALYST dose and administration

Milligram (mg) Strength: \_\_\_\_\_ Number of Capsules Dispensed: \_\_\_\_\_

**FEMALE CHILDREN (≤18 YEARS OF AGE):**

- ☐ Parent or legal guardian must have read the POMALYST REMS™ education material and agreed to ensure compliance
- ☐ Parent or legal guardian must inform the child's doctor when the child begins menses

1 of 2 (continued on next page)

The sequence of this section is based on the Education and Counseling Checklist for Pharmacies.

**Remember to fill out this checklist for every patient for every prescription.**



# Counseling for female patients of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male**, or abstaining from sex with a male
  - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
  - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

# Counseling for female patients of reproductive potential (continued)



## COUNSEL ADULTS AND CHILDREN ON:

- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

# Counseling for female patients of reproductive potential (continued)



## COUNSEL ADULTS AND CHILDREN ON:

- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use
  - Pregnancy testing should be repeated:
    - Every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all
    - If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop treatment right away **in the event of becoming pregnant, or if they think for any reason they may be pregnant**, and to call their healthcare provider immediately

# Counseling for female patients of reproductive potential (continued)



## **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

## **FOR FEMALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

# Counseling for female patients not of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

# Counseling for female patients not of reproductive potential (continued)



## FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses

# Counseling for male patients



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## **COUNSEL ADULTS AND CHILDREN ON:**

- Potential embryo-fetal toxicity and contraception
  - Wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

# Counseling for male patients (continued)



## **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

## **FOR MALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance



# Additional counseling for all patients taking POMALYST® (pomalidomide)



## COUNSEL ADULTS AND CHILDREN ON:

- Possible side effects include deep vein thrombosis and pulmonary embolism

Counsel patient to **contact healthcare provider** if experiencing any side effects.

# Pharmacy staff knowledge check



- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

**Correct Answer: C. Wearing gloves while taking capsules.**

- Patients must be counseled on:
  - Not sharing capsules with anyone—especially with females who can get pregnant
  - Not breaking, chewing, or opening capsules

## Pharmacy staff knowledge check (continued)



- Female patients of reproductive potential must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

### Correct Answer: A. True

- Female patients of reproductive potential must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

## Pharmacy staff knowledge check (continued)



- All patients must receive a Medication Guide along with their prescription.
  - A. True
  - B. False

**Correct Answer: A. True**

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

# **Celgene REMS Programs Pharmacy Training: POMALYST REMS™**

## Section 5: Guidelines for Dispensing

Celgene Confidential: For Celgene Business Use Only



## In this section



- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

# Pharmacy and prescription requirements



- Dispensing pharmacies must be certified in the applicable Celgene REMS program and educated on the program and on dispensing procedures for the treatment
- Pharmacy must ensure that every prescription includes:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature
- Authorization numbers are valid for **7 days** from the date of last pregnancy test for female patients of reproductive potential and **30 days** from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

# Dispensing guidelines



- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
  - Pharmacy must obtain a new confirmation number by calling Celgene Customer Care at 1-888-423-5436 when ready to ship or have the product picked-up



## Dispensing guidelines (continued)



- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not transfer the drug to another pharmacy without prior authorization from Celgene
- Accept unused capsules (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal

# Steps for dispensing



## Review incoming prescriptions

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

# Steps for dispensing (continued)



## Counsel patient

- Patients must receive counseling from a Celgene REMS program certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
  - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
  - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

## Steps for dispensing (continued)



### Obtain confirmation number from Celgene

- Prior to each prescription, contact Celgene Customer Care at 1-888-423-5436, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **[www.CelgeneREMSPharmacyPortal.com](http://www.CelgeneREMSPharmacyPortal.com)**. Call your Celgene Account Manager to see if your pharmacy is eligible.
  1. Enter the pharmacy NABP number or DEA number
  2. Enter the authorization number written on the prescription
  3. Enter the number of capsules and milligram strength being dispensed
  4. Write the **confirmation number** and **date** on the prescription. Note: the confirmation number is **only valid for 24 hours**
- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient

If you have questions about the validity of the authorization or confirmation numbers, call Celgene Customer Care.

# Steps for dispensing (continued)



## Dispense prescription

- Include a Medication Guide with each prescription
- Document the dispense date on either the shipping receipt or pharmacy dispensing log
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

# Pharmacy staff knowledge check



- A confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

**Correct Answer: A. 24 hours**

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

## Pharmacy staff knowledge check (continued)



- Each prescription must have both an authorization number and a patient risk category written on it.
  - A. True
  - B. False

**Correct Answer: A. True**

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature

## Pharmacy staff knowledge check (continued)



- The pharmacy must dispense no more than a 4-week (28-day) supply.
  - A. True
  - B. False

**Correct Answer: A. True**

- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide
- A new prescription is required for further dispensing



# Pomalyst REMS™

## Patient Resource Pack

### POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program

#### The Patient Resource Pack contains:


- Patient Guide to POMALYST REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.**



POMALYST® is a registered trademark of Celgene Corporation.  
POMALYST REMS™ is a trademark of Celgene Corporation.



# Patient Guide to

# Pomalyst REMS™

## Risk Evaluation and Mitigation Strategy (REMS)™ Program

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This guide provides you important information about:

- The risks of POMALYST® (pomalidomide)
  - Birth defects (deformed babies) or death of an unborn baby
  - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The POMALYST REMS™ program
  - What females who can get pregnant need to know
    - Birth control options
  - What females who can not get pregnant need to know
  - What males need to know



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## Risks of POMALYST® (pomalidomide)

POMALYST is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If POMALYST is used during pregnancy, it can cause birth defects or death to unborn babies. POMALYST must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking POMALYST.

POMALYST causes higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

## What is the POMALYST REMS™ program?

To avoid serious risks to unborn babies, POMALYST is only available under a restricted distribution program called the “POMALYST Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST. In order to receive POMALYST, patients must be enrolled in the POMALYST REMS™ program and agree to follow the requirements.

For more information about POMALYST and the POMALYST REMS™ program, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com), or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

## What do all patients need to know about the POMALYST REMS™ program?

### General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- POMALYST® (pomalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle POMALYST capsules
- Keep POMALYST in a cool, dry place
- Do **not** donate blood while you are taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST
- Unused POMALYST capsules should be returned for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you

# What do females who can get pregnant need to know about the POMALYST REMS™ program?

## A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you understand that POMALYST should not be used during pregnancy, and that you agree not to become pregnant while taking POMALYST
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking POMALYST
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for POMALYST, and again within 24 hours before you receive your first prescription for POMALYST. If you are pregnant, you cannot take POMALYST
- You will have pregnancy tests before starting POMALYST and while taking POMALYST, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

**1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control.** Talk to your healthcare provider about the following acceptable birth control methods. See below.

### Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	+ Diaphragm
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

- 2. Use the 2 methods of birth control at the same time**
- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

## What do females who can get pregnant need to know about the POMALYST REMS™ program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

### 3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield\*

### 4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for POMALYST® (pomalidomide) and again within 24 hours before receiving your first prescription for POMALYST. Both pregnancy tests must have a negative result

### B. While taking POMALYST® (pomalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
  - Every week during the first 4 weeks of treatment, then
  - Every 4 weeks if your menstrual cycles are regular, or
  - Every 2 weeks if your cycles are irregular
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking POMALYST immediately and call your healthcare provider right away

\*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

## What do females who can get pregnant need to know about the POMALYST REMS™ program? (continued)

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- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking POMALYST® (pomalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking POMALYST
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**

## C. After you have stopped taking POMALYST® (pomalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
  - For at least 4 weeks after stopping POMALYST, or
  - Do not have any sex with a male for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

## What do females who can not get pregnant need to know about the POMALYST REMS™ program?

### A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
  - You have been in natural menopause for at least 2 years, or
  - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting POMALYST
- Before your healthcare provider can write your prescription for POMALYST, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing POMALYST® (pomalidomide), your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

### B. While taking POMALYST

- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**

See “General guidelines” on page 5 for requirements for all patients.



## What do males need to know about the POMALYST REMS™ program?

- You must use a latex or synthetic condom **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

### A. Before taking POMALYST® (pomalidomide)

- You must sign the POMALYST® (pomalidomide) Patient-Physician Agreement Form. You must agree that while taking POMALYST you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing POMALYST, your POMALYST REMS™ certified pharmacy will contact you to discuss treatment

### B. While taking POMALYST

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**

- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking POMALYST® (pomalidomide) (including during breaks [dose interruptions])
- In order to continue receiving POMALYST, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your POMALYST REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

### C. After you have stopped taking POMALYST

- For 4 weeks after receiving your last dose of POMALYST, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping POMALYST

See also “General guidelines” on page 5 for requirements for all patients.

## Mandatory confidential patient surveys

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As a patient who is enrolled in the POMALYST REMS™ program for POMALYST® (pomalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

### Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

### Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

### Female children

- Initial survey before first prescription
- Monthly

### Males

- No initial survey
- Monthly

## Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a POMALYST REMS™ certified pharmacy. The POMALYST REMS™ certified pharmacy will contact you to discuss your POMALYST® (pomalidomide) therapy. You will not receive your medication until you speak with the POMALYST REMS™ certified pharmacy

For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

## Warning to patients taking POMALYST® (pomalidomide)

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### Attention females:

Do **not** take POMALYST if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

### Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking POMALYST, during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

### Attention all patients:

You must **not** donate blood while taking POMALYST® (pomalidomide), during breaks (dose interruptions), and for 4 weeks after stopping POMALYST.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

POMALYST must be kept out of the reach of children. Return any unused POMALYST capsules for disposal to Celgene by calling **1-888-423-5436**, or to your POMALYST prescriber, or to the pharmacy that dispensed the POMALYST to you.

For more information about POMALYST® (pomalidomide) and the POMALYST REMS™ program, please visit **[www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com)**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation  
86 Morris Ave  
Summit, NJ 07901

**POMALYST is only available under a restricted distribution program, POMALYST REMS™.**

**Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.**



**Pomalyst REMS™**



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